

Texas Administrative Code, Title 26, Part 1 Chapter 558 - Licensing Standards for HCSSA (Home & Community Support Agencies)

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Subchapter A, General Provisions

§558.1 Purpose

(a) Purpose.

- (1) The purpose of this chapter is to implement Texas Health and Safety Code, Chapter 142, which requires the Texas Health and Human Services Commission (HHSC) to adopt minimum standards that a person must meet in order to be licensed as a home and community support services agency (HCSSA) and also to qualify to provide certified home health services. The requirements serve as a basis for licensure and survey activities.
 - (2) Except as provided by Texas Health and Safety Code §142.003 (relating to Exemptions from Licensing Requirement), a person, including a health care facility licensed under the Texas Health and Safety Code, may not engage in the business of providing home health, hospice, or personal assistance services (PAS), or represent to the public that the person is a provider of home health, hospice, or PAS for pay without a HCSSA license authorizing the person to perform those services issued by HHSC for each place of business from which home health, hospice, or PAS is directed. A certified HCSSA must have a license to provide certified home health services.
- (b) Scope. This chapter establishes the minimum standards for acceptable quality of care. A violation of a minimum standard established by Texas Health and Safety Code Chapter 142, or by a rule adopted under that chapter, is a violation of law. The rules in this chapter are adopted to protect clients of HCSSAs by establishing minimum standards relating to quality of care and quality of life.
- (c) Limitations. Requirements established by private or public funding sources such as health maintenance organizations or other private third-party insurance, Medicaid (42 United States Code (USC) Chapter 7, Subchapter XIX), Medicare (42 USC Chapter 7, Subchapter XVIII), or state-sponsored funding programs are separate and apart from the requirements in this chapter for agencies. No matter what funding sources or requirements apply to an agency, the agency must still comply with the applicable provisions in the Statute and this chapter. The agency is responsible for researching availability of any funding source to cover a service provided by the agency.

§558.2 Definitions

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise.

- (1) Accessible and flexible services--Services that are delivered in the least intrusive manner possible and are provided in all settings where individuals live, work, and recreate.
- (2) Accreditation organization--The Joint Commission, Community Health Accreditation Partner, Accreditation Commission for Health Care, Inc., or another accrediting entity approved by HHSC that demonstrates it meets or exceeds applicable rule requirements of this chapter. The entity reviews HCSSAs for compliance with standards for accreditation by the organization that apply to a HCSSA's licensed category of service.

- (3) Administration of medication--The direct application of any medication by injection, inhalation, ingestion, or any other means to the body of a client. The preparation of medication is part of the administration of medication and is the act or process of making ready a medication for administration, including the calculation of a client's medication dosage; altering the form of the medication by crushing, dissolving, or any other method; reconstitution of an injectable medication; drawing an injectable medication into a syringe; preparing an intravenous admixture; or any other act required to render the medication ready for administration.
- (4) Administrative support site--A facility or site where an agency performs administrative and other support functions but does not provide direct home health, hospice, or personal assistance services. This site does not require an agency license.
- (5) Administrator--The person who is responsible for implementing and supervising the administrative policies and operations of a home and community support services agency and for administratively supervising the provision of all services to agency clients on a day-to-day basis.
- (6) ADS--Alternate delivery site. A facility or site, including a residential unit or an inpatient unit:
- (A) that is owned or operated by an agency providing hospice services;
 - (B) that is not the hospice's parent agency;
 - (C) that is located in the geographical area served by the hospice; and
 - (D) from which the hospice provides hospice services.
- (7) Advanced practice nurse--An advanced practice registered nurse.
- (8) Advanced practice registered nurse--A person licensed by the Texas Board of Nursing as an advanced practice registered nurse. The term is synonymous with "advanced practice nurse."
- (9) Advisory committee--A committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup, established for the purpose of obtaining advice or recommendations on issues or policies that are within the scope of a person's responsibility.
- (10) Affiliate--With respect to an applicant or license holder that is:
- (A) a corporation--means each officer, director, and stockholder with direct ownership of at least 5.0 percent, subsidiary, and parent company;
 - (B) a limited liability company--means each officer, member, and parent company;
 - (C) an individual--means:
 - (i) the individual's spouse;
 - (ii) each partnership and each partner thereof of which the individual or any affiliate of the individual is a partner; and

(iii) each corporation in which the individual is an officer, director, or stockholder with a direct ownership or disclosable interest of at least 5.0 percent.

(D) a partnership--means each partner and any parent company; and

(E) a group of co-owners under any other business arrangement--means each officer, director, or the equivalent under the specific business arrangement and each parent company.

(11) Agency-- A HCSSA.

(12) Applicant--The owner of an agency that is applying for a license under the Statute. This is the person in whose name the license will be issued.

(13) Assistance with self-administration of medication--Any needed ancillary aid provided to a client in the client's self-administered medication or treatment regimen, such as reminding a client to take a medication at the prescribed time, opening and closing a medication container, pouring a predetermined quantity of liquid to be ingested, returning a medication to the proper storage area, and assisting in reordering medications from a pharmacy. Such ancillary aid includes administration of any medication when the client has the cognitive ability to direct the administration of their medication and would self-administer if not for a functional limitation.

(14) Association--A partnership, limited liability company, or other business entity that is not a corporation.

(15) Audiologist--A person who is currently licensed under the Texas Occupations Code, Chapter 401, as an audiologist.

(16) Bereavement--The process by which a survivor of a deceased person mourns and experiences grief.

(17) Bereavement services--Support services offered to a family during bereavement. Services may be provided to persons other than family members, including residents of a skilled nursing facility, nursing facility, or intermediate care facility for individuals with an intellectual disability or related conditions, when appropriate and identified in a bereavement plan of care.

(18) Biologicals--A medicinal preparation made from living organisms and their products, including serums, vaccines, antigens, and antitoxins.

(19) Boarding home facility--An establishment defined in Texas Health and Safety Code §260.001(2).

(20) Branch office--A facility or site in the service area of a parent agency from which home health or personal assistance services are delivered or where active client records are maintained. This does not include inactive records that are stored at an unlicensed site.

(21) Care plan—

(A) a written plan prepared by the appropriate health care professional for a client of the home and community support services agency; or

- (B) for home dialysis designation, a written plan developed by the physician, registered nurse, dietitian, and qualified social worker to personalize the care for the client and enable long- and short-term goals to be met.
- (22) Case conference--A conference among personnel furnishing services to the client to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care or care plan.
- (23) Certified agency--A home and community support services agency, or portion of the agency, that:
- (A) provides a home health service; and
 - (B) is certified by an official of the U.S. Department of Health and Human Services as in compliance with Medicare conditions of participation in 42 USC Chapter 7, Subchapter XVIII.
- (24) Certified home health services--Home health services that are provided by a certified agency.
- (25) CFR--Code of Federal Regulations. The regulations and rules promulgated by agencies of the Federal government that address a broad range of subjects, including hospice care and home health services.
- (26) Change of ownership--An event that results in a change to the federal taxpayer identification number of the license holder of an agency. The substitution of a personal representative for a deceased license holder is not a change of ownership.
- (27) Chief financial officer--An individual who is responsible for supervising and managing all financial activities for a home and community support services agency.
- (28) Client--An individual receiving home health, hospice, or personal assistance services from a licensed home and community support services agency. This term includes each member of the primary client's family if the member is receiving ongoing services. This term does not include the spouse, significant other, or other family member living with the client who receives a one-time service (for example, vaccination) if the spouse, significant other, or other family member receives the service in connection with the care of a client.
- (29) Clinical note--A dated and signed written notation by agency personnel of a contact with a client containing a description of signs and symptoms; treatment and medication given; the client's reaction; other health services provided; and any changes in physical and emotional condition.
- (30) CMS--Centers for Medicare & Medicaid Services. The federal agency that administers the Medicare program and works in partnership with the states to administer Medicaid.
- (31) Complaint--An allegation against an agency regulated by HHSC or against an employee of an agency regulated by HHSC that involves a violation of this chapter or the Statute.

- (32) Community disaster resources--A local, statewide, or nationwide emergency system that provides information and resources during a disaster, including weather information, transportation, evacuation, and shelter information, disaster assistance and recovery efforts, evacuee and disaster victim resources, and resources for locating evacuated friends and relatives.
- (33) Controlled substance--Has the meaning assigned in Texas Health and Safety Code Chapter 481, Subchapter A.
- (34) Controlling person--A person with the ability, acting alone or with others, to directly or indirectly influence, direct, or cause the direction of the management, expenditure of money, or policies of an agency or other person.
- (A) A controlling person includes:
- (i) a management company or other business entity that operates or contracts with others for the operation of an agency;
 - (ii) a person who is a controlling person of a management company or other business entity that operates an agency or that contracts with another person for the operation of an agency; and
 - (iii) any other individual who, because of a personal, familial, or other relationship with the owner, manager, or provider of an agency, is in a position of actual control or authority with respect to the agency, without regard to whether the individual is formally named as an owner, manager, director, officer, provider, consultant, contractor, or employee of the agency.
- (B) A controlling person, as described by subparagraph (A)(iii) of this paragraph, does not include an employee, lender, secured creditor, or other person who does not exercise formal or actual influence or control over the operation of an agency.
- (35) Conviction--An adjudication of guilt based on a finding of guilt, a plea of guilty, or a plea of nolo contendere.
- (36) Counselor--An individual qualified under Medicare standards to provide counseling services, including bereavement, dietary, spiritual, and other counseling services to both the client and the family.
- (37) Day--Any reference to a day means a calendar day, unless otherwise specified in the text. A calendar day includes weekends and holidays.
- (38) Deficiency--A finding of noncompliance with federal requirements resulting from a survey.
- (39) Designated survey office--An HHSC HCSSA Program office located in an agency's geographic region.

- (40) Dialysis treatment record--For home dialysis designation, a dated and signed written notation by the person providing dialysis treatment, which contains a description of signs and symptoms, machine parameters and pressure settings, type of dialyzer and dialysate, actual pre- and post-treatment weight, medications administered as part of the treatment, and the client's response to treatment.
- (41) Dietitian--A person who is currently licensed under the laws of the State of Texas to use the title of licensed dietitian or provisional licensed dietitian, or who is a registered dietitian.
- (42) Direct ownership interest--Ownership of equity in the capital, stock, or profits of, or a membership interest in, an applicant or license holder.
- (43) Disaster--The occurrence or imminent threat of widespread or severe damage, injury, or loss of life or property resulting from a natural or man-made cause, such as fire, flood, earthquake, wind, storm, wave action, oil spill or other water contamination, epidemic, air contamination, infestation, explosion, riot, hostile military or paramilitary action, or energy emergency. In a hospice inpatient unit, a disaster also includes failure of the heating or cooling system, power outage, explosion, and bomb threat.
- (44) Disclosable interest--Five percent or more direct or indirect ownership interest in an applicant or license holder.
- (45) ESRD--End stage renal disease. For home dialysis designation, the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.
- (46) Functional need--Needs of the individual that require services without regard to diagnosis or label.
- (47) Habilitation--Habilitation services, as defined by Texas Government Code §534.001, provided by an agency licensed under this chapter.
- (48) HCSSA--Home and community support services agency. A person who provides home health, hospice, or personal assistance services for pay or other consideration in a client's residence, an independent living environment, or another appropriate location.
- (49) Health assessment--A determination of a client's physical and mental status through inventory of systems.
- (50) HHSC--Texas Health and Human Services Commission.
- (51) Home health aide--An individual working for an agency who meets at least one of the requirements for home health aides as described in §558.701 of this chapter (relating to Home Health Aides).
- (52) Home health medication aide--An unlicensed person issued a permit by HHSC to administer medication to a client under Texas Health and Safety Code Chapter 142, Subchapter B.
- (53) Home health service--The provision of one or more of the following health services required by an individual in a residence or independent living environment:
 - (A)nursing, including blood pressure monitoring and diabetes treatment;

- (B) physical, occupational, speech, or respiratory therapy;
 - (C) medical social service;
 - (D) intravenous therapy;
 - (E) dialysis;
 - (F) service provided by unlicensed personnel under the delegation or supervision of a licensed health professional;
 - (G) the furnishing of medical equipment and supplies, excluding drugs and medicines; or
 - (H) nutritional counseling.
- (54) Hospice--A person licensed under this chapter to provide hospice services, including a person who owns or operates a residential unit or an inpatient unit.
- (55) Hospice aide--A person working for an agency licensed to provide hospice services who meets the qualifications for a hospice aide as described in §558.843 of this chapter (relating to Hospice Aide Qualifications).
- (56) Hospice homemaker--A person working for an agency licensed to provide hospice services who meets the qualifications described in §558.845 of this chapter (relating to Hospice Homemaker Qualifications).
- (57) Hospice services--Services, including services provided by unlicensed personnel under the delegation of a registered nurse or physical therapist, provided to a client or a client's family as part of a coordinated program consistent with the standards and rules adopted under this chapter. These services include physical care and support services to optimize quality of life for terminally ill clients and their families that:
- (A) are available 24 hours a day, seven days a week, during the last stages of illness, death, and bereavement;
 - (B) are provided by a medically directed interdisciplinary team; and
 - (C) may be provided in a home, nursing facility, residential unit, inpatient unit, or other residence according to need. These services do not include inpatient care normally provided in a licensed hospital to a terminally ill person who has not elected to be a hospice client.
- (58) IDR--Informal dispute resolution. An informal process that allows an agency to refute a violation or condition-level deficiency cited during a survey.
- (59) Independent living environment--A client's residence, which may include a group home, foster home, or boarding home facility, or other settings where a client participates in activities, including school, work, or church.
- (60) Indirect ownership interest--Any ownership or membership interest in a person that has a direct ownership interest in an applicant or license holder.
- (61) Individual and family choice and control--Individuals and families who express preferences and make choices about how their support service needs are met.

- (62) Individualized service plan--A written plan prepared by the appropriate health care personnel for a client of a home and community support services agency licensed to provide personal assistance services.
- (63) Inpatient unit--A facility, also referred to as a hospice freestanding inpatient facility, that provides a continuum of medical or nursing care and other hospice services to clients admitted into the unit and that is in compliance with:
- (A) the Medicare conditions of participation for inpatient units adopted under 42 USC Chapter 7, Subchapter XVIII; and
 - (B) standards adopted under this chapter.
- (64) Joint training--Training provided by HHSC at least semi-annually for home and community support services agencies and HHSC surveyors on subjects that address the 10 most commonly cited violations of federal or state law by home and community support services agencies as published in HHSC annual reports.
- (65) LAR--Legally authorized representative. A person authorized by law to act on behalf of a client regarding a matter described in this chapter, and may include a parent of a minor, guardian of an adult or minor, managing conservator of a minor, agent under a medical power of attorney, or surrogate decision-maker under Texas Health and Safety Code §313.004.
- (66) License holder--A person that holds a license to operate an agency.
- (67) Life Safety Code (also referred to as NFPA 101)--The Code for Safety to Life from Fire in Buildings and Structures, Standard 101, of the National Fire Protection Association (NFPA).
- (68) Local emergency management agencies--The local emergency management coordinator, fire, police, and emergency medical services.
- (69) Local emergency management coordinator--The person identified as the emergency management coordinator by the mayor or county judge in an agency's service area.
- (70) LVN--Licensed vocational nurse. A person who is currently licensed under Texas Occupations Code Chapter 301, as a licensed vocational nurse.
- (71) Manager--An employee or independent contractor responsible for providing management services to a home and community support services agency for the overall operation of a home and community support services agency including administration, staffing, or delivery of services. Examples of contracts for services that will not be considered contracts for management services include contracts solely for maintenance, laundry, or food services.
- (72) Medication administration record--A record used to document the administration of a client's medications.
- (73) Medication list--A list that includes all prescription and over-the-counter medication that a client is currently taking, including the dosage, the frequency, and the method of administration.

- (74) Mitigation--An action taken to eliminate or reduce the probability of a disaster or reduce a disaster's severity or consequences.
- (75) Multiple location--A Medicare-approved ADS that meets the definition in 42 CFR §418.3.
- (76) Notarized copy--A sworn affidavit stating that attached copies are true and correct copies of the original documents.
- (77) Nursing facility--An institution licensed as a nursing home under Texas Health and Safety Code, Chapter 242.
- (78) Nutritional counseling--Advising and assisting individuals or families on appropriate nutritional intake by integrating information from the nutrition assessment with information on food and other sources of nutrients and meal preparation consistent with cultural background and socioeconomic status, with the goal being health promotion, disease prevention, and nutrition education. Nutritional counseling may include the following:
- (A) dialogue with the client to discuss current eating habits, exercise habits, food budget, and problems with food preparation;
 - (B) discussion of dietary needs to help the client understand why certain foods should be included or excluded from the client's diet and to help with adjustment to the new or revised or existing diet plan;
 - (C) a personalized written diet plan as ordered by the client's physician or practitioner, to include instructions for implementation;
 - (D) providing the client with motivation to help the client understand and appreciate the importance of the diet plan in getting and staying healthy; or
 - (E) working with the client or the client's family members by recommending ideas for meal planning, food budget planning, and appropriate food gifts.
- (79) Occupational therapist--A person who is currently licensed under the Texas Occupations Code Chapter 454, as an occupational therapist.
- (80) Online portal--A secure portal provided on the HHSC website for licensure activities, including for a HCSSA applicant to submit licensure applications and information.
- (81) Operating hours--The days of the week and the hours of day an agency's place of business is open as identified in an agency's written policy as required by §558.210 of this chapter (relating to Agency Operating Hours).
- (82) Original active client record--A record composed first-hand for a client currently receiving services.
- (83) Palliative--Ameliorating the symptoms associated with serious illness without the primary goal of curing an underlying condition.
- (84) Parent agency--An agency's principal place of business; the location where an agency develops and maintains administrative controls and provides supervision of branch offices and ADSs.

- (85) Parent company--A person, other than an individual, who has a direct 100 percent ownership interest in the owner of an agency.
- (86) Person--An individual, corporation, or association.
- (87) Personal assistance services--Routine ongoing care or services required by an individual in a residence or independent living environment that enable the individual to engage in the activities of daily living or to perform the physical functions required for independent living, including respite services. The term includes:
- (A) personal care;
 - (B) health-related services performed under circumstances that are defined as not constituting the practice of professional nursing by the Texas Board of Nursing; and
 - (C) health-related tasks provided by unlicensed personnel under the delegation of a registered nurse or that a registered nurse determines do not require delegation.
- (88) Personal care--The provision of one or more of the following services required by an individual in a residence or independent living environment:
- (A) bathing;
 - (B) dressing;
 - (C) grooming;
 - (D) feeding;
 - (E) exercising;
 - (F) toileting;
 - (G) positioning;
 - (H) assisting with self-administered medications;
 - (I) routine hair and skin care; and
 - (J) transfer or ambulation.
- (89) Pharmacist--A person who is licensed to practice pharmacy under Texas Occupations Code Chapter 558.
- (90) Pharmacy--A facility defined in Texas Occupations Code §551.003(31), at which a prescription drug or medication order is received, processed, or dispensed, and which holds a pharmacy license issued under Texas Occupations Code Title 3, Subtitle J.
- (91) Physical therapist--A person who is currently licensed under Texas Occupations Code Chapter 453, as a physical therapist.
- (92) Physician--This term includes a person who is:
- (A) licensed in Texas to practice medicine or osteopathy in accordance with Texas Occupations Code Chapter 155;

- (B) licensed in Arkansas, Louisiana, New Mexico, or Oklahoma to practice medicine, who is the treating physician of a client and orders home health or hospice services for the client, in accordance with Texas Occupations Code §151.056(b)(4); or
 - (C) a commissioned or contract physician or surgeon who serves in the United States uniformed services or Public Health Service, if the person is not engaged in private practice, in accordance with the Texas Occupations Code §151.052(a)(8).
- (93) Physician assistant--A person who is licensed under Texas Occupations Code Chapter 204, as a physician assistant.
- (94) Physician-delegated task--A task performed in accordance with Texas Occupations Code Chapter 157, including orders signed by a physician that specify the delegated task, individual to whom the task is delegated, and client's name.
- (95) Place of business--An office of a home and community support services agency that maintains client records or directs home health, hospice, or personal assistance services. This term includes a parent agency, a branch office, and an ADS. The term does not include an administrative support site.
- (96) Plan of care--The written orders of a practitioner for a client who requires skilled services.
- (97) Practitioner--A person who is currently licensed in a state in which the person practices as a physician, dentist, podiatrist, or a physician assistant, or a person who is an RN registered with the Texas Board of Nursing as an advanced practice nurse.
- (98) Preparedness--Actions taken in anticipation of a disaster.
- (99) Presurvey training--A computer-based training provided by HHSC for the applicant or the applicant's representatives to review licensure standards and survey documents, and to provide information regarding the survey process.
- (100) Progress note--A dated and signed written notation by agency personnel summarizing facts about care and the client's response during a given period of time.
- (101) Psychoactive treatment--The provision of a skilled nursing visit to a client with a psychiatric diagnosis under the direction of a physician that includes one or more of the following:
- (A) assessment of alterations in mental status or evidence of suicide ideation or tendencies;
 - (B) teaching coping mechanisms or skills;
 - (C) counseling activities; or
 - (D) evaluation of the plan of care.
- (102) Recovery--Activities implemented during and after a disaster response designed to return an agency to its normal operations as quickly as possible.
- (103) Registered nurse delegation--Delegation by a registered nurse in accordance with:

- (A) 22 TAC Chapter 224 (concerning Delegation of Nursing Tasks by Registered Professional Nurses to Unlicensed Personnel for Clients with Acute Conditions or in Acute Care Environments); and
 - (B) 22 TAC Chapter 225 (relating to RN Delegation to Unlicensed Personnel and Tasks Not Requiring Delegation in Independent Living Environments for Clients with Stable and Predictable Conditions).
- (104) Residence--A place where a person resides, including a home, a nursing facility, a convalescent home, or a residential unit.
- (105) Residential unit--A facility that provides living quarters and hospice services to clients admitted into the unit and that is in compliance with standards adopted under Texas Health and Safety Code Chapter 142.
- (106) Respiratory therapist--A person who is currently licensed under Texas Occupations Code Chapter 604, as a respiratory care practitioner.
- (107) Respite services--Support options that are provided temporarily for the purpose of relief for a primary caregiver in providing care to individuals of all ages with disabilities or at risk of abuse or neglect.
- (108) Response--Actions taken immediately before an impending disaster or during and after a disaster to address the immediate and short-term effects of the disaster.
- (109) Restraint--A restraint is:
- (A) a manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a client in a hospice inpatient unit to move his or her arms, legs, body, or head freely, but does not include a device, such as an orthopedically prescribed device, a surgical dressing or bandage, a protective helmet, or other method that involves the physical holding of the client for the purpose of:
 - (i) conducting a routine physical examination or test;
 - (ii) protecting the client from falling out of bed; or
 - (iii) permitting the client to participate in activities without the risk of physical harm, not including a physical escort; or
 - (B) a drug or medication when used as a restriction to manage a client's behavior or restrict the client's freedom of movement in a hospice inpatient unit, but not as a standard treatment or medication dosage for the client's condition.
- (110) RN--Registered nurse. A person who is currently licensed under the Nursing Practice Act, Texas Occupations Code Chapter 301, as a registered nurse.
- (111) Seclusion--The involuntary confinement of a client alone in a room or an area in a hospice inpatient unit from which the client is physically prevented from leaving.
- (112) Section--A reference to a specific rule in this chapter.
- (113) Service area--A geographic area established by an agency in which all or some of the agency's services are available.

- (114) Skilled services--Services in accordance with a plan of care that require the skills of:
- (A) an RN;
 - (B) an LVN;
 - (C) a physical therapist;
 - (D) an occupational therapist;
 - (E) a respiratory therapist;
 - (F) a speech-language pathologist;
 - (G) an audiologist;
 - (H) a social worker; or
 - (I) a dietitian.
- (115) Social worker--A person who is currently licensed as a social worker under Texas Occupations Code Chapter 505.
- (116) Speech-language pathologist--A person who is currently licensed as a speech-language pathologist under Texas Occupations Code Chapter 401.
- (117) Statute--Texas Health and Safety Code Chapter 142.
- (118) Substantial compliance--A finding in which an agency receives no recommendation for enforcement action after a survey.
- (119) Supervised practical training--Hospice aide training that is conducted in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual. The training is supervised by an RN or by an LVN who works under the direction of a registered nurse.
- (120) Supervising nurse--The person responsible for supervising skilled services provided by an agency and who has the qualifications described in §558.244(c) of this chapter (relating to Administrator Qualifications and Conditions and Supervising Nurse Qualifications). This person may also be known as the director of nursing or similar title.
- (121) Supervision--Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity.
- (122) Supportive palliative care--Physician-directed interdisciplinary patient and family-centered care provided to a patient with a serious illness without regard to the patient's age or terminal prognosis that:
- (A) may be provided concurrently with methods of treatment or therapies that seek to cure or minimize the effects of the patient's illness; and
 - (B) seek to optimize the quality of life for a patient with a life-threatening or life-limiting illness and the patient's family through various methods, including methods that seek to:
 - (i) anticipate, prevent, and treat the patient's total suffering related to the patient's physical, emotional, social, and spiritual condition;

- (ii) address the physical, intellectual, emotional, cultural, social, and spiritual needs of the patient; and
 - (iii) facilitate for the patient, regarding treatment options, education, informed consent, and expression of desires.
- (123) Support services--Social, spiritual, and emotional care provided to a client and a client's family by a hospice.
- (124) Survey--An on-site inspection or complaint investigation conducted by an HHSC representative to determine if an agency is in compliance with the Statute and this chapter or in compliance with applicable federal requirements or both.
- (125) TAC--Texas Administrative Code.
- (126) Terminal illness--An illness for which there is a limited prognosis if the illness runs its usual course.
- (127) Unlicensed person--A person not licensed as a health care provider. The term includes home health aides, hospice aides, hospice homemakers, medication aides permitted by HHSC, and other unlicensed individuals providing personal care or assistance in health services.
- (128) Unsatisfied judgments--A failure to fully carry out the terms or meet the obligation of a court's final disposition on the matters before it in a suit regarding the operation of an agency.
- (129) Violation--A finding of noncompliance with this chapter or the Statute resulting from a survey.
- (130) Volunteer--An individual who provides assistance to a home and community support services agency without compensation other than reimbursement for actual expenses.
- (131) Working day--Any day except Saturday, Sunday, a state holiday, or a federal holiday.

§558.3 License Fee

- (a) The schedule of fees for licensure of an agency authorized to provide one or more services is as follows:
 - (1) initial (includes change of ownership) license fee--\$2,625;
 - (2) renewal license fee for a three-year license--\$2,625;
 - (3) renewal license fee for a two-year license--\$1,750;
 - (4) initial (includes change of ownership) branch office license fee--\$2,625;
 - (5) renewal branch office license fee for a three-year license--\$2,625;
 - (6) renewal branch office license fee for a two-year license--\$1,750;
 - (7) initial (includes change of ownership) ADS license fee--\$1,000;
 - (8) renewal ADS license fee for a three-year license--\$900; and
 - (9) renewal ADS license fee for a two-year license--\$600.

- (b) Separate fees for branch office and ADS licenses and renewals are required for each physical address. To renew a branch office or ADS license, the licensee must submit the renewal application and payment in full, of all applicable licensing fees, for each branch office and ADS sought to be renewed, at the same time as the parent agency submission for renewal.
- (c) A late fee assessed under Subchapter B of this chapter (relating to Criteria and Eligibility, Application Procedures, and Issuance of a License) is one-half the amount of the required renewal license fee established in subsection (a) of this section. If HHSC assesses a late fee described in this subsection, the applicant must pay the applicable renewal application fee in full plus the late fee described in this section. HHSC may assess a separate late fee for each parent agency, branch office, and ADS renewal application.
- (d) If an applicant for an initial license based on a change of ownership submits a late application for a license to HHSC, as described in §558.25 of this chapter (relating to Requirements for Change of Ownership), the applicant must pay the required initial license fee, as set out in subsection (a) of this section, plus a late fee of \$250.
- (e) HHSC does not review an application until the applicant submits the application and the online portal reflects a status of payment received.
- (f) A fee paid to HHSC is not refundable but may be reimbursed under the circumstances and conditions described in §558.31 of this chapter (relating to Time Frames for Processing and Issuing a License).
- (g) HHSC accepts payment of required fees made in accordance with options made available through the online portal.

Subchapter B, Criteria and Eligibility, Application Procedures, and Issuance of License

§558.11 Criteria and Eligibility for Licensing

- (a) An applicant for a license must not admit a client or initiate services until the applicant completes the application process and receives an initial license.
- (b) A first-time application for a license is an application for an initial license.
- (c) An application for a license when there is a change of ownership is an application for an initial license.
- (d) A separate license is required for each place of business as defined in §558.2 of this chapter (relating to Definitions).
- (e) An agency's place of business must be located in and have an address in Texas. An agency located in another state must receive a license as a parent agency in Texas to operate as an agency in Texas.
- (f) An applicant must be at least 18 years of age.
- (g) Before issuing a license, HHSC considers the background of:
 - (1) the applicant;
 - (2) a controlling person of the applicant;
 - (3) a person with a disclosable interest;
 - (4) an affiliate of the applicant;
 - (5) the chief financial officer.

- (h) Before issuing a license, HHSC considers the background and qualifications of the administrator and alternate administrator in accordance with §558.244 of this chapter (relating Administrator Qualifications and Conditions and Supervising Nurse Qualifications).
- (i) HHSC may deny an application for an initial license or for renewal of a license if a person described in subsection (g) or (h) of this section:
 - (1) on the date of the application:
 - (A) is subject to denial or refusal as described in Chapter 560 of this title (relating to Denial or Refusal of License) during the time frames described in that chapter;
 - (B) has an unsatisfied final judgment in any state or other jurisdiction;
or
 - (C) is delinquent on child support obligations (Texas Family Code Chapter 232);
 - (2) for two years preceding the date of the application, has a history in any state or other jurisdiction of any of the following:
 - (A) an unresolved federal or state tax lien;
 - (B) an eviction involving any property or space used as an inpatient hospice agency; or
 - (C) an unresolved final Medicare or Medicaid audit exception; or
 - (3) for 12 months preceding the date of the application, has a history in any state or other jurisdiction of any of the following:
 - (A) denial, suspension, or revocation of an agency license or a license for a health care facility;
 - (B) surrendering a license before expiration or allowing a license to expire instead of the licensing authority proceeding with enforcement action;
 - (C) a Medicaid or Medicare sanction or penalty relating to the operation of an agency or a health care facility;
 - (D) operating an agency that has been decertified in any state under Medicare or Medicaid; or
 - (E) debarment, exclusion, or involuntary contract cancellation in any state from Medicare or Medicaid.

§558.12 General Application

- (a.) An applicant must submit an application on the forms prescribed by HHSC through the online portal.
- (b.) An applicant must complete and furnish all documents and information that HHSC requests in accordance with instructions provided with the application. All uploaded documents an applicant submits must be complete and accurate. If an applicant provides incorrect or false information, or withholds information, on an application, HHSC may:
 - (1.) deny the application; or
 - (2.) assess an administrative penalty, as described in §558.602(e)(5) of this chapter (relating to Administrative Penalties).
- (c.) When an applicant submits an application through the online portal with full payment of applicable license fees, HHSC reviews the application and supporting documents to determine if it is complete and accurate. A complete and accurate application includes all documents and information that HHSC requests as part of the application process.
 - (1.) HHSC processes the application in accordance with time frames established in §558.31 of this subchapter (relating to Time Frames for Processing and Issuing a License).
 - (2.) If an applicant decides not to continue the application process for a license after submitting the application and license fee, the applicant must submit a written request to HHSC to withdraw the application. HHSC does not refund the license fee.
- (d.) If an application is not complete and accurate, HHSC provides the applicant with electronic notice through the online portal, that the application is incomplete and specifies the information required to complete the application.
 - (1.) The applicant must submit to HHSC, through the online portal, the additional information requested to complete the application by no later than 30 days after the date of the notice. HHSC sends only one electronic notice through the online portal of the information needed to complete the application.
 - (2.) If an applicant fails to submit the required information to complete the application within 30 days after HHSC provides electronic notice through the online portal, HHSC considers the application incomplete and may deny the application. If HHSC denies the application, HHSC does not refund the license fee.
 - (3.) HHSC, at its discretion, may accept information later than 30 days based on extenuating circumstances. HHSC may assess the late fee authorized in §558.3(c) and set out in §558.3(d) of this chapter (relating to License Fees) for the parent agency and any applicable branch offices or ADSs for failure to comply with paragraph (1) of this subsection.
- (e.) HHSC may deny issuance of a license for any of the reasons specified in §558.21 of this subchapter (relating to Denial of an Application or a License).

§558.13 Obtaining an Initial License

- (a.) The following staff must complete the Presurvey Training before submitting an application for a license:
 - (1.) the administrator and alternate administrator; and
 - (2.) the supervising nurse and alternate supervising nurse of an agency that provides licensed home health services with or without home dialysis designation, licensed and certified home health services with or without home dialysis designation, or hospice services.
- (b.) An applicant may request to be licensed in one or more of the following categories:
 - (1.) licensed and certified home health services;
 - (2.) licensed and certified home health services with home dialysis designation;
 - (3.) licensed home health services;
 - (4.) licensed home health services with home dialysis designation;
 - (5.) hospice services; or
 - (6.) personal assistance services.
- (c.) HHSC does not require an agency to be licensed in more than one category if the category for which the agency is licensed includes the services the agency provides.
- (d.) An applicant who has requested the category of licensed and certified home health services on the initial license application must also apply to CMS for certification as a Medicare-certified agency under the 42 United States Code Chapter 7, Subchapter XVIII.
 - (1.) While the applicant is waiting for CMS to certify it as a Medicare-certified agency:
 - (A) HHSC issues an initial license reflecting the category of licensed home health services if the applicant meets the criteria for the license; and
 - (B) the applicant must comply with the Medicare conditions of participation for home health agencies in 42 CFR Part 484, as if the applicant were dually certified.
 - (2.) If CMS certifies an agency to participate in the Medicare program during the initial license period, HHSC sends a notice to the agency that the category of licensed and certified home health services has been added to the license. If the agency wants to remove the licensed home health services category from the agency's license after the category of licensed and certified home health services has been added, the agency must submit to HHSC an application through the online portal to remove that category from the agency's license.
 - (3.) If CMS denies certification to an agency or an agency withdraws the application for participation in the Medicare program, the agency may retain the category of licensed home health services on its license.

- (e.) An applicant for an initial license must comply with §558.30 of this subchapter (relating to Operation of an Inpatient Unit at a Parent Agency) to operate an inpatient unit at the applicant's parent agency.

§558.15 Issuance of an Initial License

- (a.) HHSC issues an initial license when HHSC determines:
 - (1.) the application, including supporting documents, submitted are complete and accurate;
 - (2.) HHSC has received funds constituting full payment of all applicable license fees, including late fees; and
 - (3.) an applicant meets the criteria for a license as described in §558.11 of this subchapter (relating to Criteria and Eligibility for Licensing) and §558.13 of this subchapter (relating to Obtaining an Initial License).
- (b.) An initial license is valid for three years from the date of issuance.
- (c.) HHSC may deny an application to renew an initial license, or revoke or suspend an initial license, if an agency fails to:
 - (1.) meet the requirements for an initial survey as specified in Subchapter E of this chapter (relating to Licensure Surveys); or
 - (2.) maintain compliance with the Statute and this chapter for the services authorized under the license.
- (d.) HHSC may deny an application for an initial license for any of the reasons specified in §558.21 of this chapter (relating to Denial of an Application or a License).
- (e.) A license designates an agency's place of business from which services are to be provided and designates an agency's authorized category or categories of service.

§558.17 Application Procedures for a Renewal License

- (a.) To renew its license, an agency must submit a renewal application through the online portal.
- (b.) An agency must submit its renewal application in accordance with §558.12 of this subchapter (relating to General Application) when submitting a renewal application through the online portal.
- (c.) For each license period, an agency must provide services to at least one client to be eligible to renew its license.
- (d.) HHSC does not require an agency to admit a client under each category of service authorized under the license to be eligible to renew its license.
- (e.) With each renewal application, an agency accredited by an accreditation organization referenced in §558.503 of this chapter (relating to Exemption from Survey) must submit to HHSC through the online portal a copy of the accreditation documentation that the agency receives from the accreditation organization.
- (f.) At least 120 days before the expiration date of a license, HHSC makes the renewal application and instructions available through the online portal. HHSC notifies the agency with electronic notice that the application and instructions to renew the license are made available through the online portal.

- (1.) If the renewal application is not made available by HHSC in accordance with this subsection, the agency must, at least 90 days before the expiration date of a license, notify HHSC in writing that it has not received notice of expiration and request that HHSC make a renewal application available.
 - (2.) To avoid a late fee, an agency must submit to HHSC a complete and accurate renewal application, as described in §558.12(c) of this subchapter, with full payment of all required license fees as specified in §558.3 of this chapter (relating to License Fees), no later than the 45th day before the expiration date of the license.
 - (3.) If an agency submits a renewal application after the 45th day before the expiration date of a license, but before the expiration date of the license, HHSC assesses the late fee set out in §558.3(c) of this chapter for failure to comply with paragraph (2) of this subsection.
- (g.) If an agency submits a renewal application to HHSC after the expiration date of the license, HHSC denies the renewal application and does not refund the renewal license fee. The agency is not eligible to renew the license and must cease operation on the date the license expires. An agency whose license expires must apply for an initial license in accordance with §558.13 of this subchapter (relating to Obtaining an Initial License).
- (h.) If an agency submits a renewal application before the expiration date of the license in accordance with this subsection, the license does not expire until HHSC has made a final determination on the application.
- (1.) If an enforcement action is pending at the time the renewal applicant submits a renewal application, the agency's license does not expire and the agency may continue to operate until HHSC had made a final determination on the application, concurrent with the agency's opportunity for a formal hearing as described in §558.601 of this chapter (relating to Enforcement Actions).
 - (2.) A license expires if the license holder fails to submit a renewal application in accordance with the subsection before the expiration date.
- (i.) If a license holder fails to submit a renewal application in accordance with subsection (h) of this section because the license holder is or was on active duty with the armed forces of the United States of America outside the State of Texas, the license holder may renew the license pursuant to this subsection.
- (1.) An individual having power of attorney from the license holder or other authority to act on behalf of the license holder may request renewal of the license. The renewal application must include a current address and telephone number for the individual requesting the renewal.
 - (2.) An agency may submit a request for a renewal application through the online portal before or after the expiration of the license.
 - (3.) A copy of the official orders or other official military documentation showing that the license holder is or was on active military duty serving outside the State of Texas must be submitted to HHSC with the renewal application.
 - (4.) A copy of the power of attorney from the license holder or other authority to act on behalf of the license holder must be submitted to HHSC with the renewal application.
 - (5.) A license holder applying to renew a license under this subsection must pay the required renewal fee in full.
 - (6.) A license holder may not operate the agency for which the license was obtained after the expiration of the license unless and until HHSC renews the license.

- (7.) This subsection applies to a license holder who is an individual or a partnership comprised of individuals, all of whom are or were on active duty with the armed forces of the United States of America serving outside the State of Texas.
- (j.) An applicant for a renewal license must comply with §558.30 of this subchapter (relating to Operation of an Inpatient Unit at a Parent Agency) to operate an inpatient unit at the applicant's parent agency.

§558.19 Issuance of a Renewal License

- (a.) A license issued under this chapter expires three years after the date HHSC issues it, except as provided in subsections (e)(1) and (f)(1) of this section.
- (b.) Except as specified in §558.503 of this chapter (relating to Exemption From a Survey), HHSC may not renew an initial license unless HHSC conducts an initial survey of the agency. For renewal of an initial license, an agency must:
 - (1.) meet the requirements for an initial survey as specified in Subchapter E of this chapter (relating to Licensure Surveys);
 - (2.) demonstrate substantial compliance with the Statute and this chapter for the services authorized under the license as confirmed by an initial survey; and
 - (3.) apply for renewal of the license in accordance with §558.17 of this subchapter (relating to Application Procedures for a Renewal License).
- (c.) For renewal of a license other than an initial license, an agency must:
 - (1.) maintain substantial compliance with the Statute and this chapter for the services authorized under the license; and
 - (2.) apply for renewal of the license in accordance with §558.17 of this subchapter.
- (d.) If HHSC grants the renewal application, it issues a renewal license effective on the day after the previous license expires.
- (e.) If HHSC renews a license that expires after December 31, 2020, and before January 1, 2022, HHSC:
 - (1.) issues a license that is valid for two years, if the license is for an agency with a license number that ends in 0-3 or 7-9; and
 - (2.) issues a license that is valid for three years, if the license is for an agency with a license number that ends in 4-6.
- (f.) If HHSC renews a license that expires after December 31, 2020, and before January 1, 2023, HHSC:
 - (1.) issues a license that is valid for two years, if the license is for an agency with a license number that ends in 4-6; and
 - (2.) issues a license that is valid for three years, if the license is for an agency with a license number that ends in 0-3 or 7-9.
- (g.) HHSC may deny a renewal application:
 - (1.) if an agency fails to meet the eligibility criteria in §558.11 of this subchapter (relating to Criteria and Eligibility for Licensing);
 - (2.) if the agency fails to meet the requirements for renewal of a license as specified in this subchapter; or

(3.) for any of the reasons specified in §558.21 of this subchapter (relating to Denial of an Application or a License).

(h.) A renewal license designates an agency's place of business from which services are to be provided or directed and designates an agency's authorized category or categories of service.

§558.21 Denial of an Application or a License

(a.) HHSC may deny an application for a license on any ground described in this chapter, or if any person described in §558.11(g) or (h) of this subchapter (relating to Criteria and Eligibility for Licensing):

- (1.) fails to comply with the Statute;
- (2.) fails to comply with this chapter;
- (3.) knowingly aids, abets, or permits another person to violate the Statute or this chapter;
- (4.) fails to meet the criteria for a license established in §558.11 of this subchapter;
or
- (5.) violates Texas Occupations Code §102.001.

(b.) If HHSC denies an application for a license, the applicant or agency may request an administrative hearing in accordance with §558.601 of this chapter (relating to Enforcement Actions).

§558.23 Change of Ownership

(a.) A license holder may not transfer its license. If there is a change of ownership, the license holder's license becomes invalid on the date of the licensure change of ownership. The prospective license holder must apply for a license in accordance with §558.12 of this subchapter (relating to General Application) and §558.13 of this subchapter (relating to Obtaining an Initial License).

(b.) If HHSC grants the application for an initial change of ownership license and allows an initial change of ownership application to occur without a gap in the agency's licensed status, the license holder at the time of the application must maintain an active and valid license until HHSC grants and issues an initial license to the change of ownership applicant.

(c.) A change of ownership for a parent agency is a change of ownership for the parent agency's branch office or ADS and requires the submittal of an application and license fee for each branch office and ADS at the same time as the parent agency application and fee.

(d.) HHSC conducts an on-site health inspection to verify compliance with the licensure requirements after issuing a license as a result of a change of ownership. HHSC may conduct a desk review instead of an on-site health inspection after issuing a license as a result of a change of ownership if:

- (1.) less than 50 percent of the direct or indirect ownership interest in the former license holder changed, when compared to the new license holder; or

(2.) every owner with a disclosable interest in the new license holder had a disclosable interest in the former license holder.

(e.) For an agency licensed to provide licensed and certified home health services or certified, as well as licensed, to provide hospice services, applicable federal laws and regulations relating to change of ownership or control apply in addition to the requirements of this section.

§558.25 Requirements for Change of Ownership

To apply for an initial change of ownership license, a prospective new owner must submit an initial license application to HHSC through the online portal in accordance with paragraph (2) of this subsection. The application must be complete and accurate, as described in §558.12(c) of this subchapter (relating to General Application), and the applicant must submit the appropriate license fee with the application.

(1.) The change of ownership applicant must submit the complete and accurate initial application with full payment of required license fees at least 30 days before the anticipated date of sale or other transfer of ownership and before the expiration date of the license.

(A) HHSC may accept a change of ownership application less than 30 days before the effective date.

(B) HHSC may assess a late fee set out in §558.3(d) of this chapter (relating to License Fees).

(2.) The change of ownership applicant must apply for the initial license in accordance with §558.23(a) of this subchapter (relating to Change of Ownership) and meet the criteria for a license as described in §558.11 of this subchapter (relating to Criteria and Eligibility for Licensing) and §558.13 of this subchapter (relating to Obtaining an Initial License).

(3.) If an applicant submits a complete and accurate application through the online portal, has met all the criteria for a license, and HHSC has received funds constituting full payment of all required license fee HHSC issues the change of ownership applicant an initial license. The effective date of the license constitutes the licensure change of ownership date.

(4.) The initial license issued to the new owner is valid for three years from the date of issuance.

§558.27 Application and Issuance of an Initial Branch Office License

(a.) An agency with a current license to provide licensed home health services, licensed and certified home health services, or personal assistance services may qualify for a branch office license, if the parent agency:

(1.) is found to be in substantial compliance with the Statute and this chapter;

(2.) has no enforcement action pending against the license; and

(3.) meets its initial survey requirements before HHSC approves a branch office license.

- (b.) To apply for a branch office license, an agency must submit an application for the license to HHSC through the online portal, in accordance with §558.12 of this subchapter (relating to General Application).
- (c.) A designated survey office conducts a review of an agency's request to establish a branch office. The survey office makes a recommendation to approve or disapprove the branch office request.
- (d.) HHSC approves or denies the application for a branch office license after considering the designated survey office's recommendation. If HHSC denies the application, HHSC sends the agency a written notice:
 - (1.) of its decision; and
 - (2.) the agency's opportunity to appeal its decision through a formal hearing process as described in §558.601 of this chapter (relating to Enforcement Actions).
- (e.) CMS approves or denies the branch location if an agency is licensed to provide licensed and certified home health services.
- (f.) A branch office license expires on the same expiration date as the parent agency's license. To renew a branch office license, the license holder must submit, to HHSC through the online portal, a complete and accurate renewal application and all required fees for the branch office license application, and the agency may renew it with the parent agency's license.
- (g.) If HHSC grants a branch office license, it provides the branch office license to the license holder for the parent agency and branch office. The branch office must post the license in a conspicuous place on the licensed branch office premises.
- (h.) A branch office must comply with §558.321 of this title (relating to Standards for Branch Offices) and the additional standards that relate to the agency's authorized categories under the license.
- (i.) Unless an agency is exempt from the survey, as specified in §558.503 of this chapter (relating to Exemption From a Survey), HHSC does not renew a branch office license if it has not conducted a health survey of a branch office after issuance of the license to verify compliance with the Statute and this chapter.

§558.29 Application and Issuance of an Alternate Delivery Site License

- (a.) An agency with a license to provide hospice services may qualify for an ADS license if the parent agency:
 - (1.) is in substantial compliance with the Statute and this chapter; and
 - (2.) has no enforcement action pending against its license.
- (b.) To apply for an ADS license, an agency must submit an ADS application to HHSC through the online portal, in accordance with §558.12 of this subchapter (relating to General Application).
 - (1.) In the application, an agency may request to operate an inpatient unit at the ADS location.

- (2.) To add an inpatient unit to a licensed ADS, an agency must submit a change of service category application through the online portal according to the instructions for requesting HHSC approval, and otherwise comply with requirements of this section.
- (c.) After an agency submits an application for an ADS with an inpatient unit, the agency must contact the HHSC Architectural Unit to request a Life Safety Code survey. Before HHSC considers whether the application is complete, HHSC determines an agency's compliance with the Life Safety Code requirements §558.871 of this chapter (relating to Physical Environment in a Hospice Inpatient Unit).
- (d.) A designated survey office reviews an agency's application for an ADS license and makes a recommendation to the HHSC HCSSA licensing unit whether to approve or deny the application. The HCSSA licensing unit approves or denies the agency's application.
- (e.) If HHSC denies an agency's application, HHSC sends the agency a written notice:
 - (1.) informing the agency of its decision; and
 - (2.) providing the agency with an opportunity to appeal its decision through a formal hearing process as described in §558.601 of this chapter (relating to Enforcement Actions).
- (f.) Except as provided in subsection (g) of this section, after HHSC issues a license for an ADS with an inpatient unit, the agency must, after providing inpatient services to a client, submit the Notification of Readiness for a Health Survey of a Hospice Inpatient Unit (HHSC Form 2020-A), to the designated survey office. HHSC conducts an initial licensure health survey to review the requirements in §558.871 of this chapter specified in Subchapter H, Division 7 of this chapter (relating to Hospice Inpatient Units) that an HHSC Life Safety Code surveyor did not review during the initial Life Safety Code survey.
- (g.) An agency is not required to request an initial licensure health survey of an ADS with an inpatient unit if the agency is exempt from the health survey as specified in §558.503 of this chapter (relating to Exemption From a Survey). To demonstrate that it is exempt, the agency must send the accreditation documentation from the accreditation organization to the HHSC designated survey office within seven days after the agency receives the accreditation documentation.
- (h.) If an agency receives accreditation documentation from the accreditation organization after the agency submits a written request to HHSC for an initial licensure health survey, the agency may demonstrate that it is exempt from the survey by sending the accreditation documentation to the HHSC designated survey office before HHSC arrives at the agency to conduct an initial health survey.
- (i.) A Medicare-certified hospice agency must also submit a request to CMS for approval of an ADS, including an ADS with an inpatient unit. CMS approves or denies the request.

- (j.) An ADS license expires on the same date the parent agency's license expires. To renew an ADS license, the license holder must submit to HHSC through the online portal a renewal application and all required fees for the ADS license when submitting a renewal application for the parent agency's license.
- (k.) If HHSC grants an ADS license, it will provide the license to the parent agency. The agency must post the ADS license in a conspicuous place on the licensed ADS premises.
- (l.) An ADS must comply with the Statute and this chapter, including the applicable additional standards for hospice agencies in Subchapter H of this chapter (relating to Standards Specific to Agencies Licensed to Provide Hospice Services) and §558.322 of this chapter (relating to Standards for Alternate Delivery Sites). A Medicare-certified hospice agency's ADS must also comply with the applicable federal rules and regulations for hospice agencies in 42 CFR Part 418.

§558.30 Operation of an Inpatient Unit at a Parent Agency

- (a.) To operate an inpatient unit at a parent agency, the license holder for the parent agency or an applicant for an initial license to provide hospice services must:
 - (1.) submit an initial parent application through the online portal according to applicable instructions for requesting HHSC approval to operate an inpatient unit at the parent agency;
 - (2.) send written notice to HHSC that it is ready for a Life Safety Code inspection through the online portal;
 - (3.) allow HHSC to conduct an on-site Life Safety Code inspection to determine if the inpatient unit is in compliance with §558.871 of this chapter (relating to Physical Environment in a Hospice Inpatient Unit);
 - (4.) obtain verification from HHSC that the inpatient unit is in compliance with Subchapter H, Division 7 of this chapter (relating to Hospice Inpatient Units) before admitting a client to the inpatient unit;
 - (5.) after HHSC issues a license authorizing the inpatient unit, admit and provide hospice services to a client in the inpatient unit; and
 - (6.) except as provided in subsection (c) of this section:
 - (A) submit the Notification of Readiness for a Health Survey of a Hospice Inpatient Unit (HHSC Form 2020-A) to HHSC after admitting and providing services to at least one client in the inpatient unit; and
 - (B) be determined by HHSC to be in substantial compliance with the Statute and this chapter, including Subchapter H of this chapter (relating to Standards Specific to Agencies Licensed to Provide Hospice Services).
- (b.) If the applicant is currently licensed at the time an agency notifies HHSC in accordance with subsection (a)(1) of this section, the agency must not have enforcement action pending against the license under which the agency would operate the inpatient unit.
- (c.) An agency that provides hospice services is not required to submit the Notification of Readiness for a Health Survey of a Hospice Inpatient Unit (HHSC Form 2020-A) in

accordance with subsection (a)(6)(A) of this section if the agency demonstrates that it is exempt from a health survey, as described in §558.503 of this chapter (relating to Exemption From a Survey). The agency may demonstrate that it is exempt from the initial health survey described in §558.521 of this chapter (relating to Requirements for an Initial Survey) by submitting the accreditation documentation from an approved accreditation organization referenced in §558.503 of this chapter to the designated HHSC survey office within seven days after the agency receives the accreditation documentation.

- (d.) If HHSC grants an application for an initial parent agency license with an inpatient unit or to add an inpatient unit to a licensed parent agency, the licensed agency and the license holder must comply with the Statute and this chapter, including Subchapter H of this chapter.

§558.31 Time Frames for Processing and Issuing a License

(a.) General.

- (1.) In this section, the date of an application is the date an applicant successfully submits an application to HHSC through the online portal as described in subsection (b)(1) of this section.
- (2.) HHSC considers an application complete for purposes of this section when it is complete and accurate as described in §558.12 of this subchapter (relating to General Applications), and the applicant has met all requirements for licensure, including applicable background and survey standards before HHSC issues a license.

(b.) Time frames. HHSC processes an application in accordance with the following time frames.

- (1.) The first time frame begins on the date the applicant successfully submits an application through the online portal and the online portal reflects a status of "payment received" for applicable license fees, including late fees, and ends on the date HHSC determines the submission is complete and accurate, as described in §558.12 of this subchapter (relating to General Applications). If HHSC receives an incomplete application, the first time frame ends on the date HHSC sends an electronic notice, through the online portal, to the agency that the application is incomplete. The electronic notice specifies the information that the applicant must submit to complete the application. The first time frame is no longer than 45 days.
- (2.) The second time frame begins on the date that the application is complete, as described for the purpose of this section, in subsection (a)(2) of this section, and ends on the date the license is issued. The second time frame is no longer than 45 days.
- (3.) If an agency is subject to a proposed or pending enforcement action on its license, on or within 45 days before the expiration date of the license, HHSC may postpone decision on a renewal application while the action is pending.

(c.) Reimbursement of fees.

- (1.) If HHSC does not process the application in the time frames stated in subsection (b) of this section, the applicant has the right to request that HHSC reimburse the license fee. If HHSC does not agree that the established time frames have been violated or finds that good cause existed for exceeding the established time frames, HHSC denies the request.
- (2.) HHSC considers that good cause for exceeding the established time frames exists if:
- (A) the number of applications to be processed exceeds by 15 percent or more the number of applications processed in the same quarter for the preceding year;
 - (B) another public or private entity used in the application process caused the delay; or
 - (C) other conditions existed giving good cause for exceeding the established time frames.
- (d.) Appeal. If HHSC denies the request for reimbursement of the license fee, as authorized by subsection (c) of this section, the applicant may appeal the denial. In order to appeal, the applicant must send a written request for reimbursement of the license fee to the HHSC executive commissioner. The request must include that the application was not processed within the established time frame. The HHSC HCSSA licensing unit provides the HHSC executive commissioner with a written report of the facts related to the processing of the application and good cause for exceeding the established time frame. The HHSC executive commissioner makes the final decision and provides written notification of the decision to the applicant and the HHSC HCSSA licensing unit.

Subchapter C, Minimum Standards for All Home and Community Support Services Agencies

Division 1 General Provisions

§558.201 Applicability

- (a) This subchapter applies to a home and community support services agency providing licensed home health services or licensed and certified home health services with and without home dialysis designation, hospice services, or personal assistance services.
- (b) In addition to the minimum standards in this subchapter, an agency must also comply with applicable standards in Subchapter D of this chapter (relating to Additional Standards Specific to License Category and Specific to Special Services) and Subchapter H of this chapter (relating to Standards Specific to Agencies Licensed to Provide Hospice Services).

§558.202 Habilitation

- (a) An agency may provide habilitation.
- (b) An agency that provides habilitation must provide habilitation in accordance with this chapter, including any licensure standards in Subchapter D of this chapter (relating to Additional Standards Specific to License Category and Specific to Special Services) that apply to the categories of service designated on the agency's license.

Division 2 Conditions of a License

§558.208 Reporting Changes in Application Information and Fees

- (a.) If certain information provided on an initial or renewal application changes after HHSC issues the license, an agency must report the change to HHSC via the online portal. The agency must use the Home and Community Support Services Agency License Application, (HHSC Form 2021) to report the change. To avoid a late fee, an agency must report a change as required in this subsection and pay in full applicable fees required under subsection (b) of this section, within the time frame specified for the type of change.
- (1.) For requirements on reporting a change in the agency's location, see §558.213 of this division (relating to Agency Relocation);
 - (2.) For requirements on reporting a change in the agency's contact information and operating hours, see §558.214 of this division (relating to Notification Procedures for a Change in Agency Contact Information and Operating Hours);
 - (3.) For requirements on reporting a change to the agency's name, see §558.215 of this division (relating to Notification Procedures for an Agency Name Change);
 - (4.) For requirements on reporting a change in the agency's organizational management personnel, see §558.218 of this division (relating to Agency Organizational Changes);
 - (5.) For requirements on adding or deleting a category of service to the license, see §558.219 of this division (relating to Procedures for Adding or Deleting a Category to the License); and
 - (6.) For requirements on expanding or reducing the agency's service area, see §558.220 of this division (relating to Service Areas).
- (b.) The schedule of fees an agency must pay when the agency timely submits HHSC Form 2021, to report changes in application information, is as follows.
- (1.) An agency is not required to pay a fee if the agency reports changes to contact information and operating hours, within the required time frame, as specified in §558.214 of this division.
 - (2.) An agency is not required to pay a fee if the agency reports a change in the alternate administrator, within the required time frame, as specified in §558.218 of this division.
 - (3.) An agency must pay a fee of \$30 if the agency, within the required time frame, reports one or more of the following changes:
 - (A) a change in physical location, as specified in §558.213 of this division;
 - (B) a change in name (legal entity or doing business as), as specified in §558.215 of this division;
 - (C) a change in administrator, chief financial officer, or controlling person, as specified in §558.218 of this division;

(D) a change in category of service designated on a license, as specified in §558.219 of this division; or

(E) a change in service area, as specified in §558.220 of this division.

(4.) HHSC does not consider a change of information as officially submitted until the online portal reflects a status of payment received, if a fee is applicable.

(c.) If an agency untimely submits HHSC Form 2021 to report one or more changes referenced in subsection (a) of this section, the agency must pay a late fee of \$100. If an agency must pay a fee of \$30 for reporting a change referenced in subsection (b)(3) of this section, the \$100 late fee is in addition to the \$30 fee.

(d.) If HHSC determines, based on review of an agency's renewal application, that an agency did not report a change in application information as required by this section, HHSC notifies the agency in writing of the fee amount due for payment.

(e.) If HHSC determines, based on a survey, that an agency did not report a change in application information as required by this section, HHSC notifies the agency in writing of the fee amount due for payment. Reporting the change and paying the required fee does not preclude HHSC from taking other enforcement action against the agency as specified in §558.601 of this chapter (relating to Enforcement Actions).

(f.) If an agency pays a fee to HHSC to report a change in application information, the fee is not refundable. HHSC accepts payment for a required fee as described in §558.3(f) of this chapter (relating to License Fees).

(g.) HHSC may suspend or revoke a license or deny an application for a renewal license if an agency does not pay a fee, as required by this section, within 30 days after HHSC provides written notice of a fee amount due for payment. Within 10 days after receipt of HHSC's written notice of a fee amount due for payment, an agency may submit proof to HHSC that the agency:

(1.) submitted HHSC Form 2021 to timely report a change in application information, as specified in each rule referenced in subsection (a) of this section; and

(2.) paid the fee amount required by this section when the agency submitted HHSC Form 2021.

§558.210 Agency Operating Hours

(a.) An agency must adopt and enforce a written policy identifying the agency's operating hours.

(b.) For the purposes of this section, the person in charge means the administrator, the designated alternate administrator, the supervising nurse, or the alternate supervising nurse.

(c.) If an agency is closed during the agency's operating hours or between the hours of 8:00 a.m. and 5:00 p.m. Monday through Friday, the person in charge must:

(1.) post a notice in a visible location outside the agency that will provide information regarding how to contact the person in charge; and

- (2.) leave a message on an answering machine or similar electronic mechanism that will provide information regarding how to contact the person in charge.

§558.211 Display of License

The license must be displayed in a conspicuous place in the designated place of business. If the information on the license is officially amended during the licensure period, a notice must be posted beside the license to provide public notice of the change.

§558.212 License Alteration Prohibited

A license may not be altered.

§558.213 Agency Relocation

- (a.) An agency must not transfer a license from one location to another without prior notice to HHSC. If an agency is considering relocation, the agency must submit written notice to HHSC to report a change in physical location at least 30 days before the intended relocation, unless HHSC grants the agency an exemption from the 30-day time frame as specified in subsection (b) of this section. A change in physical location for a hospice inpatient unit requires HHSC to conduct a survey to approve the new location.
- (b.) An agency must notify HHSC immediately if an unexpected situation beyond the agency's control makes it impossible for the agency to submit written notice to HHSC no later than 30 days before the agency relocates. HHSC grants or denies the exemption.
 - (1.) If HHSC grants the exemption, the agency must submit written notice to HHSC as described in subsection (c) of this section within 30 days after the date HHSC grants the exemption.
 - (2.) If HHSC denies the exemption, the agency may not relocate until at least 30 days after the agency submits the written notice to HHSC, as described in subsection (c) of this section.
- (c.) An agency must report a change in physical location to HHSC in accordance with §558.208 of this division (relating to Reporting Changes in Application Information and Fees).
- (d.) If an agency reports a change in physical location, the agency must pay a fee and may be subject to a late fee, as described in §558.208 of this division.
- (e.) HHSC sends the agency a Notification of Change reflecting the new location. The agency must post the Notification of Change beside its license in accordance with §558.211 of this division (relating to Display of License).
- (f.) A Medicare certified home health and hospice agency must comply with applicable federal laws and regulations and the requirements of this section for reporting an agency relocation. A change in physical location for a Medicare-certified agency requires HHSC review.
- (g.) An agency is exempt from the requirements in subsections (a) - (d) of this section when reporting a temporary relocation that results from the effects of an emergency or disaster, as specified in §558.256(o) of this subchapter (relating to Emergency Preparedness Planning and Implementation).

§558.214 Notification Procedures for a Change in Agency Contact Information and Operating Hours

- (a.) An agency must report to HHSC no later than seven days after a change in the agency's:
 - (1.) telephone number;
 - (2.) mailing address, if different than the physical location; or
 - (3.) operating hours.
- (b.) An agency must report the changes described in subsection (a) of this section to HHSC in accordance with §558.208 of this division (relating to Reporting Changes in Application Information and Fees).
- (c.) If an agency reports the information after the timeframes required by this section, the agency must pay a late fee as described in §558.208 of this division.

§558.215 Notification Procedures for an Agency Name Change

- (a.) If an agency intends to change its name (legal entity or assumed (doing business as) name), but does not undergo a change of ownership as defined in §558.23(c) of this chapter (relating to Change of Ownership), the agency must report the name change to HHSC no later than seven days after the effective date of the name change.
- (b.) An agency must report a name change to HHSC in accordance with §558.208 of this division (relating to Reporting Changes in Application Information and Fees).
- (c.) If an agency reports a name change, the agency must pay a fee and may be subject to a late fee, as described in §558.208 of this division (relating to Reporting Changes in Application Information and Fees).
- (d.) After HHSC receives and verifies the required documents and information, HHSC sends the agency a Notification of Change reflecting the agency's new name. The agency must post the Notification of Change beside its license in accordance with §558.211 of this division (relating to Display of License).

§558.216 Change in Agency Certification Status

- (a.) An agency must notify HHSC in writing no later than five days after the agency decides to voluntarily withdraw from the Medicare program. If an agency's voluntary withdrawal from the Medicare program is based on the permanent closure of the agency, the agency must also comply with §558.217 of this division (relating to Agency Closure Procedures and Voluntary Suspension of Operations).
- (b.) If an agency chooses to voluntarily withdraw from the Medicare program, or if CMS involuntarily terminates or denies its certification, the license will be affected as follows:
 - (1.) If an agency licensed to provide licensed and certified home health services has no other license categories remaining on the license after losing its Medicare certification, its license is void and the agency must cease operation. If the agency wants to resume providing services, it must apply for an initial license.
 - (2.) If a Medicare-certified agency has another license category remaining on the current license and the agency wants to continue providing services under the

remaining license category, HHSC surveys the agency under the remaining license category.

- (c.) As specified in §558.601(c)(2) of this chapter (relating to Enforcement Actions), HHSC may take enforcement action against an agency licensed to provide licensed and certified home health services if the agency fails to maintain its Medicare certification. The agency may request an administrative hearing in accordance with §558.601 of this chapter to contest the enforcement action taken by HHSC against the agency.

§558.217 Agency Closure Procedures and Voluntary Suspension of Operations

- (a.) Permanent closure. An agency must notify HHSC in writing within five days before the permanent closure of the agency, branch office, or ADS.
- (1.) The agency must include in the written notice the reason for closing, the location of the client records (active and inactive), and the name and address of the client record custodian.
 - (2.) If the agency closes with an active client roster, the agency must transfer a copy of the active client record with the client to the receiving agency in order to ensure continuity of care and services to the client.
 - (3.) The agency must mail or return the initial license or renewal license to HHSC at the end of the day that services cease.
 - (4.) If an agency continues to operate after the closure date specified in the notice, HHSC may take enforcement action against the agency.
- (b.) Applicability. This subsection applies to an agency licensed to provide licensed home health services, personal assistance services, and licensed-only hospice services.
- (1.) Voluntary suspension of operations occurs when an agency voluntarily suspends its normal business operations for 10 or more consecutive days. A voluntary suspension of operations may not last longer than the licensure renewal period. If an agency voluntarily suspends operations, the agency must:
 - (A) discharge or arrange for backup services for active clients;
 - (B) provide written notification to the designated survey office at least five days before the voluntary suspension of operations, or within two working days before the voluntary suspension of operations, if an emergency occurs that is beyond the agency's control; and
 - (C) post a notice of voluntary suspension of operations on the entry door of the agency and leave a voice message that informs callers of the voluntary suspension of operations.
 - (2.) An agency must notify the HHSC HCSSA licensing unit in writing no later than seven days after resuming operations.

§558.218 Agency Organizational Changes

- (a.) If a change occurs in the following management personnel, an agency must submit written notice to HHSC no later than seven days after the date of a change in:
- (1.) administrator;

- (2.)alternate administrator;
 - (3.)chief financial officer; or
 - (4.)controlling person, as defined in §558.2 of this chapter (relating to Definitions).
- (b.)An agency must report a change in the management personnel listed in subsection (a) of this section to HHSC in accordance with §558.208 of this division (relating to Reporting Changes in Application Information and Fees).
 - (c.)If an agency reports a change in the administrator, chief financial officer, or controlling person, the agency must pay a fee and may be subject to a late fee, as described in §558.208 of this division.
 - (d.)An agency is not required to pay a fee to report a change in alternate administrator, but the agency must pay a late fee, as described in §558.208 of this division, if the agency does not report the change within the time frame required in this section.
 - (e.)A change in the management personnel listed in subsection (a) of this section requires HHSC evaluation and approval. HHSC reviews the required documents and information submitted. HHSC notifies an agency if the information the agency provides does not reflect that a person listed in subsection (a)(1) - (4) of this section meets the required qualifications.

§558.219 Procedures for Adding or Deleting a Category to the License

- (a.)To add or delete a category of service to a license, an agency must submit the appropriate application to HHSC through the online portal at least 30 days before adding or deleting the category.
- (b.)HHSC either approves or denies the application to add a category of service no later than 30 days after HHSC receives the application through the online portal. An agency must not provide the services under the category the agency is adding until the agency receives written notice of approval from HHSC.
 - (1.)To add a category of service to a license, an agency must:
 - (A) be in substantial compliance with the Statute and this chapter; and
 - (B) have no enforcement action pending against the license.
 - (2.)If HHSC denies the application to add a category of service, HHSC informs the agency of the reason for denial.
 - (3.)HHSC may conduct a survey after the approval of a category.
- (c.)An agency's submission of an application to delete a category from a license does not preclude HHSC from taking enforcement action as appropriate in accordance with Subchapter F of this chapter (relating to Enforcement)
- (d.)An agency must submit to HHSC the application to add or delete a category of service in accordance with §558.208 of this division (relating to Reporting Changes in Application Information and Fees).
- (e.)If an agency submits an application to add or delete a category of service, the agency must pay a fee and may be subject to a late fee, as described in §558.208 of this division.

- (f.) If HHSC grants an agency's application to add or delete a category of service, HHSC sends the agency a Notification of Change reflecting the change in the category of service. The agency must post the Notification of Change beside its license in accordance with §558.211 of this division (relating to Display of License).

§558.220 Service Areas

- (a.) An agency must identify its licensed service area. A branch office or ADS must be located within the parent agency's licensed service area. An agency must not provide services outside its licensed service area, except as provided in subsections (i) and (j) of this section.
- (b.) An agency must maintain adequate staff to provide services and to supervise the provision of services.
- (c.) An agency may expand its service area at any time during the licensure period. An agency must submit an application to HHSC through the online portal to expand the agency's service area at least 30 days before the expansion, unless HHSC grants the agency an exemption from the 30-day time frame as specified in subsection (d) of this section.
 - (1.) An agency must notify HHSC immediately of a possible emergency situation that would affect client health and safety.
 - (2.) HHSC grants or denies an exemption from the 30-day application submission requirement.
 - (A) If HHSC grants an exemption, the agency must submit an application to HHSC through the online portal, as described in subsection (e) of this section, no later than 30 days after the date HHSC grants the exemption.
 - (B) If HHSC denies an exemption, the agency may not expand the agency's service area until at least 30 days after the agency submits the written notice to HHSC, as described in subsection (e) of this section.
- (d.) An agency is exempt from the requirement to submit an application to HHSC through the online portal no later than 30 days before the agency expands its service area if HHSC determines an emergency situation exists that would affect client health and safety.
- (e.) If an agency intends to expand or reduce the agency's service area, the agency must submit an application to HHSC through the online portal, in accordance with §558.208 of this subchapter (relating to Reporting Changes in Application Information and Fees).
- (f.) If an agency reports a change in service area, the agency must pay a fee and may be subject to a late fee, as described in §558.208 of this subchapter.
- (g.) An agency may reduce its service area at any time during the licensure period. An agency must submit an application to HHSC through the online portal informing HHSC that the agency reduced its service area, no later than 10 days after the reduction.
- (h.) HHSC sends the agency a Notification of Change reflecting the change in service area. An agency is not required to post the Notification of Change in service area beside its license.

- (i.) An agency is exempt from the requirements described in subsections (c) - (f) of this section if a temporary expansion results from an emergency or disaster, as specified in §558.256(o) of this subchapter (relating to Emergency Preparedness Planning and Implementation).
- (j.) An agency may provide services to a client outside the agency's licensed service area, but within the State of Texas, in accordance with this subsection and, for an agency licensed to provide hospice services, with the additional standards in §558.830 of this chapter (relating to Provision of Hospice Core Services).
 - (1.) The agency may provide the services for no more than 60 consecutive days, unless the agency expands its service area as described in subsections (e) and (f) of this section.
 - (2.) The client must reside in the agency's service area and be receiving services from the agency at the time the client leaves the agency's service area.
 - (3.) The agency must maintain compliance with the Statute and this chapter and, if applicable, federal home health and hospice regulations.
 - (4.) The agency must document in the client record the start and end dates for the services
 - (5.) An agency's authority to provide services to a client outside its service area may depend on regulations or requirements established by the client's private or public funding source, including a health maintenance organization or other private third-party insurance; Medicaid, under 42 United States Code Chapter 7, Subchapter XVIII; or a state-funded program. The agency is responsible for knowing these requirements.
- (k.) If a client notifies an agency that the client is leaving the agency's service area and the agency does not provide services in accordance with subsection (j) of this section, the agency must inform the client that leaving the agency's service area requires the agency to:
 - (1.) place the client's services on hold in accordance with the agency's written policy, required by §558.281 of this subchapter (relating to Client Care Policies), until the client returns to the agency's service area;
 - (2.) transfer and discharge the client in accordance with §558.295 of this subchapter (relating to Client Transfer or Discharge Notification Requirements) and the agency's written policy required by §558.281 of this subchapter; or
 - (3.) discharge the client in accordance with §558.295 of this subchapter and the agency's written policy required by §558.281 of this subchapter.

§558.222 Compliance

An agency must maintain satisfactory compliance with all the provisions of the Statute and this chapter to maintain licensure.

Division 3, Agency Administration

§558.241 Management

- (a.) Agency policies. The license holder is responsible for the conduct of the agency and for the adoption, implementation, enforcement, and monitoring of adherence to the written policies required throughout this chapter. The license holder is also responsible for ensuring that the policies comply with the Statute and the applicable provisions of this chapter and are administered to provide safe, professional, quality health care.
- (b.) Criminal conviction. The persons described in §558.11(g) of this chapter (relating to Criteria and Eligibility for Licensing) must not have been convicted of an offense described in §560.2 of this title (relating to Convictions Barring Licensure), during the time frames described in that section.
- (c.) Documentation. The license holder must ensure that all documents submitted to HHSC, or maintained by the agency pursuant to this chapter, are accurate and do not misrepresent or conceal a material fact.
- (d.) Compliance with enforcement orders. The license holder must comply with an order of the HHSC executive commissioner or other enforcement orders that may be imposed on the agency in accordance with the Statute and this chapter.

§558.242 Organizational Structure and Lines of Authority

- (a.) An agency must prepare and maintain a current written description of the agency's organizational structure. The document may be either in the form of a chart or a narrative.
- (b.) The description must include:
 - (1.) all services provided by the agency;
 - (2.) the governing body, administrator, supervising nurse, advisory committee, interdisciplinary team, and staff, as appropriate, based on services provided by the agency; and
 - (3.) the lines of authority and the delegation of responsibility down to and including the client care level.

§558.243 Administrative and Supervisory Responsibilities

- (a.) Administrative responsibilities.
 - (1.) A license holder, or the license holder's designee, must designate an individual who meets the qualifications and conditions set out in §558.244 of this division (relating to Administrator Qualifications and Conditions and Supervising Nurse Qualifications) to serve as the administrator of the agency.
 - (2.) A license holder, or the license holder's designee, must designate in writing an alternate administrator who meets the qualifications and conditions of an administrator to act in the absence of the administrator.
- (b.) Administrator responsibilities.
 - (1.) An administrator must be responsible for implementing and supervising the administrative policies and operations of the agency and for administratively

supervising the provision of all services to agency clients on a day-to-day basis. An administrator must:

- (A) manage the daily operations of the agency;
- (B) organize and direct the agency's ongoing functions;
- (C) administratively supervise the provision of quality care to agency clients;
- (D) supervise to ensure implementation of agency policy and procedures;
- (E) ensure that the documentation of services provided is accurate and timely;
- (F) employ or contract with qualified personnel;
- (G) ensure adequate staff education and evaluations, according to requirements in §558.245(b) of this division (relating to Staffing Policies);
- (H) ensure the accuracy of public information materials and activities;
- (I) implement an effective budgeting and accounting system that promotes the health and safety of the agency's clients; and
- (J) supervise and evaluate client satisfaction survey reports on all clients served.

(2.) An administrator or alternate administrator must be available to agency personnel, in person or by telephone, during the agency's operating hours and in accordance with the rules in this chapter, including §558.210 of this subchapter (relating to Agency Operating Hours), §558.404(h)(2) of this chapter (relating to Standards Specific to Agencies Licensed to Provide Personal Assistance Services), §558.523 of this chapter (relating to Personnel Requirements for a Survey), and §558.527 of this chapter (relating to Post-Survey Procedures).

(3.) An administrator must designate, in writing, an agency employee who must provide HHSC surveyors entry to the agency in accordance with §558.523(e) of this chapter (relating to Personnel Requirements for a Survey), if the administrator and alternate administrator are not available.

(c.) Supervision of services.

(1.) Except as provided in paragraph (3) of this subsection, an agency licensed to provide licensed home health services, licensed and certified home health services, or hospice services must directly employ or contract with an individual who meets the qualifications in §558.244 of this division to serve as the supervising nurse.

(2.) An agency must designate, in writing, a similarly qualified alternate to serve as supervising nurse in the absence of the supervising nurse.

- (A) The supervising nurse or alternate supervising nurse must:

- i. always be available to agency personnel, in person or by telephone;
- ii. participate in activities relevant to services furnished, including the development of qualifications and assignment of agency personnel;
- iii. ensure that a client's plan of care or care plan is executed as written; and
- iv. ensure that an appropriate health care professional performs a reassessment of a client's needs:
 - I. when there is a significant health status change in the client's condition;
 - II. at the physician's request; or
 - III. after hospital discharge.

(B) A supervising nurse may also be the administrator of the agency, if the supervising nurse meets the qualifications and conditions of an administrator described in §558.244(a) and (b) of this division.

(3.) An agency that provides only physical, occupational, speech or respiratory therapy, medical social services, or nutritional counseling is not required to employ or contract with a supervising nurse. A qualified licensed professional must supervise these services, as applicable.

(d.) Supervision of branch offices and ADSs. An agency must adopt and enforce a written policy relating to the supervision of branch offices or ADSs, if established. This policy must be consistent with the following:

- (1.) for a branch office, §558.27 of this chapter (relating to Application and Issuance of an Initial Branch Office License) and §558.321 of this chapter (relating to Standards for Branch Offices); or
- (2.) for an ADS, §558.29 of this chapter (relating to Application and Issuance of an Alternate Delivery Site License) and §558.322 of this chapter (relating to Standards for Alternate Delivery Sites).

§558.244 Administrator Qualifications and Conditions and Supervising Nurse Qualifications

(a.) Administrator qualifications.

(1.) For an agency licensed to provide licensed home health services, licensed and certified home health services, or hospice services, the administrator and the alternate administrator must:

- (A) be a licensed physician, RN, licensed social worker, licensed therapist, or licensed nursing home administrator with at least one year of management or supervisory experience in a health-related setting, such as:
 - i. a home and community support services agency;

- ii. a hospital;
- iii. a nursing facility;
- iv. a hospice;
- v. an outpatient rehabilitation center;
- vi. a psychiatric facility;
- vii. an intermediate care facility for individuals with an intellectual disability or related conditions; or
- viii. a licensed health care delivery setting providing services for individuals with functional disabilities; or

(B) have a high school diploma or a general equivalency degree (GED) with at least two years of management or supervisory experience in a health-related setting, such as:

- i. a home and community support services agency;
- ii. a hospital;
- iii. a nursing facility;
- iv. a hospice;
- v. an outpatient rehabilitation center;
- vi. a psychiatric facility;
- vii. an intermediate care facility for individuals with an intellectual disability or related conditions; or
- viii. a licensed health care delivery setting providing services for individuals with functional disabilities.

(2.) For an agency licensed to provide hospice services, in addition to the qualifications listed in paragraph (1)(A) or (B) of this subsection, the administrator and the alternate administrator must:

(A) be a hospice employee; and

(B) have any additional education and experience required by the hospice's governing body, as specified in the agency's job description.

(3.) For an agency licensed to provide only personal assistance services, the administrator and the alternate administrator must meet at least one of the following qualifications:

(A) have a high school diploma or a GED with at least one year of experience or training in caring for individuals with functional disabilities;

(B) have completed two years of full-time study at an accredited college or university in a health-related field; or

- (C) meet the qualifications listed in paragraph (1)(A) or (B) of this subsection.

(b.) Administrator conditions.

- (1.) An administrator and alternate administrator must be able to read, write, and comprehend English.
- (2.) An administrator and alternate administrator designated as an administrator or alternate administrator for the first time on or after December 1, 2006, must meet the initial educational training requirements specified in §558.259 of this division (relating to Initial Educational Training in Administration of Agencies).
- (3.) An administrator and alternate administrator designated as an administrator or alternate administrator before December 1, 2006, must meet the continuing education requirements specified in §558.260 of this division (relating to Continuing Education in Administration of Agencies).
- (4.) A person is not eligible to be the administrator or alternate administrator of any agency if the person was the administrator of an agency cited with a violation that resulted in HHSC taking enforcement action against the agency while the person was the administrator of the cited agency.
 - (A) This paragraph applies for 12 months after the date of the enforcement action.
 - (B) For purposes of this paragraph, enforcement action means license revocation, suspension, emergency suspension of a license, denial of an application for a license, or the imposition of an injunction, but it does not include administrative or civil penalties.
 - (C) If HHSC prevails in one enforcement action against the agency and proceeds with, but does not prevail in, another enforcement action based on some or all of the same violations, this paragraph does not apply.
- (5.) An administrator and alternate administrator must not be convicted of an offense described in Chapter 560 of this title (relating to Denial or Refusal of License) during the time frames described in that chapter.

(c.) Supervising nurse qualifications.

- (1.) For an agency without a home dialysis designation, a supervising nurse and alternate supervising nurse must each:
 - (A) be an RN licensed in Texas or in accordance with the Texas Board of Nursing rules for Nurse Licensure Compact (NLC); and
 - (B) have at least one year of experience as an RN within the last 36 months.
- (2.) For an agency with home dialysis designation, a supervising nurse and alternate supervising nurse must each:
 - (A) be an RN licensed in Texas or in accordance with the Texas Board of Nursing rules, 22 TAC Chapter 220 for NLC, and:

- i. have at least three years of current experience in hemodialysis; or
 - ii. have at least two years of experience as an RN and hold a current certification from a nationally recognized board in nephrology nursing or hemodialysis; or
- (B) be a nephrologist or physician with training or demonstrated experience in the care of ESRD clients.

§558.245 Staffing Policies

(a.) An agency must adopt and enforce written staffing policies that govern all personnel used by the agency, including employees, volunteers, and contractors.

(b.) An agency's written staffing policies must:

- (1.) include requirements for orientation to the policies, procedures, and objectives of the agency;
- (2.) include requirements for participation by all personnel in job-specific training. Agency training program policies must:
 - (A) ensure personnel are properly oriented to tasks performed;
 - (B) ensure demonstration of competency for tasks when competency cannot be determined through education, license, certification, or experience;
 - (C) ensure a continuing systematic program for the training of all personnel; and
 - (D) ensure personnel are informed of changes in techniques, philosophies, goals, client's rights, and products relating to client's care;
- (3.) address participation by all personnel in appropriate employee development programs;
- (4.) include a written job description (statement of those functions and responsibilities that constitute job requirements) and job qualifications (specific education and training necessary to perform the job) for each position within the agency;
- (5.) include procedures for processing criminal history checks and searches of the nurse aide registry and the employee misconduct registry for unlicensed personnel in accordance with §558.247 of this division (relating to Verification of Employability and Use of Unlicensed Persons);
- (6.) ensure annual evaluation of employee and volunteer performance;
- (7.) address employee and volunteer disciplinary action and procedures;
- (8.) address the use of volunteers, if volunteers are used by the agency. The policy must be in compliance with §558.248 of this division (relating to Volunteers);
- (9.) address requirements for providing and supervising services to pediatric clients. Services provided to pediatric clients must be provided by staff who have been instructed and have demonstrated competency in the care of pediatric clients; and

- (10.) include a requirement that all personnel who are direct care staff and who have direct contact with clients (employed by or under contract with the agency) sign a statement that they have read, understand, and will comply with all applicable agency policies.

§558.246 Personnel Records

- (a.) An agency must maintain a personnel record for an employee and volunteer. A personnel record may be maintained electronically if it meets the same requirements as a paper record. All information must be kept current. A personnel record must include the following:

- (1.) a signed job description and qualifications for each position accepted, or a signed statement that the person read the job description and qualifications for each position accepted;
- (2.) an application for employment or volunteer agreement;
- (3.) verification of license, permits, references, job experience, and educational requirements, as conducted by the agency to verify qualifications for each position accepted;
- (4.) performance evaluations and disciplinary actions;
- (5.) the signed statement about compliance with agency policies required by §558.245(b)(10) of this division (relating to Staffing Policies), if applicable; and
- (6.) for an unlicensed employee and unlicensed volunteer whose duties would or do include face-to-face contact with a client:
 - (A) a printed copy of the results of the initial and annual searches of the nurse aide registry (NAR) and employee misconduct registry (EMR) obtained from the HHSC website; and
 - (B) documentation that the employee, in accordance with §558.247(a)(4) of this division (relating to Verification of Employability and Use of Unlicensed Persons), or volunteer, in accordance with §558.247(b)(4) of this division, received written information about the EMR.

- (b.) An agency may keep a complete and accurate personnel record for an employee and volunteer in any location, as determined by the agency. An agency must provide personnel records not stored at the site of a survey upon request by a HHSC surveyor, as specified in §558.507(c) of this chapter (relating to Agency Cooperation with a Survey).

§558.247 Verification of Employability and Use of Unlicensed Persons

- (a.) The provisions in this subsection apply to an unlicensed applicant for employment and an unlicensed employee, if the person's duties would or do include face-to-face contact with a client.
 - (1.) An agency must conduct a criminal history check authorized by, and in compliance with, Texas Health and Safety Code Chapter 250 (relating to Nurse Aide Registry and Criminal History Checks of Employees and Applicants for

Employment in Certain Facilities Serving the Elderly, Persons with Disabilities, or Persons with Terminal Illnesses) for an unlicensed applicant for employment and an unlicensed employee.

- (2.) The agency must not employ an unlicensed applicant whose criminal history check includes a conviction listed in Texas Health and Safety Code §250.006 that bars employment, or a conviction the agency has determined is a contraindication to employment. If an applicant's or employee's criminal history check includes a conviction of an offense that is not listed in Texas Health and Safety Code §250.006, the agency must document its review of the conviction and its determination of whether the conviction is a contraindication to employment.
- (3.) Before the agency hires an unlicensed applicant, or before an unlicensed employee's first face-to-face contact with a client, the agency must search the nurse aide registry (NAR) and the employee misconduct registry (EMR) using the HHSC website to determine if the applicant or employee is listed in either registry as unemployable. The agency must not employ an unlicensed applicant who is listed as unemployable in either registry.
- (4.) The agency must provide written information about the EMR to an unlicensed employee in compliance with the requirements of 40 TAC §93.3(c) (relating to Employment and Registry Information).
- (5.) In addition to the initial verification of employability, the agency must search the NAR and the EMR to determine if the employee is listed as unemployable in either registry as follows:
 - (A) for an employee most recently hired before September 1, 2009, by August 31, 2011, and at least every twelve months thereafter; and
 - (B) for an employee most recently hired on or after September 1, 2009, at least every 12 months.
- (6.) The agency must immediately discharge an unlicensed employee whose duties would or do include face-to-face contact with a client when the agency becomes aware:
 - (A) that the employee is designated in the NAR or the EMR as unemployable; or
 - (B) that the employee's criminal history check reveals conviction of a crime that bars employment or that the agency has determined is a contraindication to employment.
- (b.) The provisions in this subsection apply to an unlicensed volunteer if the person's duties would or do include face-to-face contact with a client.
 - (1.) An agency must conduct a criminal history check before an unlicensed volunteer's first face-to-face contact with a client of the agency.
 - (2.) The agency must not use the services of an unlicensed volunteer for duties that would or do include face-to-face contact with a client whose criminal history information includes a conviction that bars employment under Texas Health and

Safety Code §250.006 or a conviction the agency has determined is a contraindication to employment. If an unlicensed volunteer's criminal history check includes a conviction of an offense that is not listed in Texas Health and Safety Code §250.006, the agency must document its review of the conviction and its determination of whether the conviction is a contraindication to employment.

- (3.) Before an unlicensed volunteer's first face-to-face contact with a client, the agency must conduct a search of the NAR and the EMR using the HHSC website to determine if an unlicensed volunteer is listed in either registry as unemployable. The agency must not use the services of an unlicensed volunteer who is listed as unemployable in either registry.
- (4.) The agency must provide written information about the EMR that complies with the requirements of 40 TAC §93.3(c) to an unlicensed volunteer within five working days from the date of the person's first face-to-face contact with a client.
- (5.) In addition to the initial verification of employability, the agency must search the NAR and the EMR to determine if a volunteer is designated in either registry as unemployable, as follows:
 - (A) for a volunteer with face-to-face contact with a client for the first time before September 1, 2009, by August 31, 2011, and at least every twelve months thereafter; and
 - (B) for a volunteer with face-to-face contact with a client for the first time on or after September 1, 2009, at least every twelve months.
- (6.) The agency must immediately stop using the services of an unlicensed volunteer for duties that would or do include face-to-face contact with a client when the agency becomes aware that:
 - (A) the unlicensed volunteer is designated in the NAR or the EMR as unemployable; or
 - (B) the unlicensed volunteer's criminal history check reveals conviction of a crime that bars employment or that the agency has determined is a contraindication to employment.
- (c.) Upon request by HHSC, an agency must provide documentation to demonstrate compliance with subsections (a) and (b) of this section.
- (d.) An agency that contracts with another agency or organization for an unlicensed person to provide home health services, hospice services, or personal assistance services under arrangement must also comply with the requirements in §558.289(c)-(d) of this subchapter (relating to Independent Contractors and Arranged Services).

§558.248 Volunteers

- (a.) This section applies to all licensed agencies. However, agencies certified by CMS to provide hospice services also must comply with 42 CFR §418.78, Conditions of Participation--Volunteers.
- (b.) If an agency uses volunteers, the agency must use volunteers in defined roles under the supervision of a designated agency employee.

- (1.) A volunteer must meet the same requirements and standards in this chapter that apply to agency employees performing the same activities.
- (2.) An agency may use volunteers in administrative and direct client care roles.
- (3.) Volunteers must document services provided to a client and, if applicable, services provided to the client's family.

§558.249 Self-Reported Incidents of Abuse, Neglect, and Exploitation

(a.) The following words and terms, when used in this section or §558.250 of this division (relating to Agency Investigations), have the following meanings, unless the context clearly indicates otherwise.

(1.) Abuse, neglect, and exploitation--Have the meanings assigned by:

- (A) Chapter 711, Subchapter A of this title (relating to Introduction), if the term is used in connection with alleged conduct against a child or an adult receiving services from certain providers, as defined in Texas Human Resources Code §48.251, or against a child receiving services from an agency, as that term is defined in this chapter, whose employee is the alleged perpetrator; or
- (B) 40 TAC Chapter 705, Subchapter A (relating to Definitions), if the term is used in connection with alleged conduct against an adult, other than as described in subparagraph (A) of this paragraph.

(2.) Adult--A client who is:

- (A) 18 years of age or older; or
- (B) under 18 years of age who:
 - i. is or has been married; or
 - ii. has had the disabilities of minority removed pursuant to the Texas Family Code Chapter 31.

(3.) Agent--An individual (e.g., student, volunteer), not employed by but working under the auspices of an agency.

(4.) Cause to believe--An agency knows, suspects, or receives an allegation regarding abuse, neglect, or exploitation.

(5.) Child--A client under 18 years of age who:

- (A) is not and has not been married; or
- (B) has not had the disabilities of minority removed pursuant to the Texas Family Code Chapter 31.

(6.) Employee--An officer, an individual directly employed by an agency or a contractor, volunteer, or agent working under the auspices of an agency.

(b.) An agency must adopt and enforce a written policy relating to the agency's procedures for reporting alleged acts of abuse, neglect, and exploitation of a client by an employee of the agency.

(c.) If an agency has cause to believe that a client served by the agency has been abused, neglected, or exploited by an agency employee, the agency must report the information immediately, meaning within 24 hours, to:

(1.) the Department of Family and Protective Services (DFPS) at 1-800-252-5400, or through the DFPS secure website at www.txabusehotline.org; and

(2.) HHSC at 1-800-458-9858.

§558.250 Agency Investigations

(a.) Written policy.

(1.) An agency must adopt and enforce a written policy relating to the agency's procedures for investigating complaints and reports of abuse, neglect, and exploitation.

(2.) The policy must meet the requirements of this section.

(b.) Reports of abuse, neglect, and exploitation (ANE).

(1.) Immediately upon witnessing the act or upon receipt of the allegation, an agency must initiate an investigation of known and alleged acts of ANE by agency employees, including volunteers and contractors.

(2.) An agency must complete an HHSC Provider Investigation Report form and include the following information:

- (A) incident date;
- (B) the name of the alleged victim;
- (C) the age of the alleged victim at the time of the incident;
- (D) the name of the alleged perpetrator;
- (E) any witnesses;
- (F) the allegation;
- (G) any injury or adverse effect;
- (H) any assessments made;
- (I) any treatment required;
- (J) the investigation summary; and
- (K) any action taken.

(3.) An agency must send the completed HHSC Provider Investigation Report form to HHSC Complaint Intake Unit no later than the 10th day after reporting the act to the Department of Family and Protective Services and HHSC.

(c.) Agency complaint investigations.

(1.) An agency must investigate complaints made by a client, a client's family or guardian, or a client's health care provider, in accordance with this subsection, regarding:

- (A) treatment or care that was furnished by the agency;
- (B) treatment or care that the agency failed to furnish; or
- (C) a lack of respect for the client's property by anyone furnishing services on behalf of the agency.

(2.) An agency must:

- (A) document receipt of the complaint and initiate a complaint investigation within 10 days after the agency's receipt of the complaint; and
- (B) document all components of the investigation.

(d.) Completing agency investigations. An agency must complete the investigation and documentation within 30 days after the agency receives a complaint or report of abuse, neglect, and exploitation, unless the agency has and documents reasonable cause for a delay.

(e.) Retaliation.

(1.) An agency may not retaliate against a person for filing a complaint, presenting a grievance, or providing, in good faith, information relating to home health, hospice, or personal assistance services provided by the agency.

(2.) An agency is not prohibited from terminating an employee for a reason other than retaliation.

§558.251 Peer Review

An agency must adopt and enforce a written policy to ensure that all professional disciplines comply with their respective professional practice acts or title acts relating to reporting and peer review.

§558.252 Financial Solvency and Business Records

An agency must have the financial ability to carry out its functions.

- (1.) An agency must not intentionally or knowingly pay employees or contracted staff with checks from accounts with insufficient funds.
- (2.) An agency must have sufficient funds to meet its payroll.
- (3.) An agency must make available to HHSC, upon request, business records relating to its ability to carry out its functions. If there is a question relating to the accuracy of the records or the agency's financial ability to carry out its functions, HHSC or its designee may conduct a more extensive review of the records.
- (4.) An agency must maintain business records in their original state. Each entry must be accurate and dated with the date of entry. Correction fluid or tape may not be used in the record. Corrections must be made in accordance with standard accounting practices.

§558.253 Disclosure of Drug Testing Policy

- (a.) An agency must have a written policy describing whether it will conduct drug testing of its employees who have direct contact with clients.

- (b.) If an agency conducts drug testing, the written policy must describe the method by which drug testing is conducted.
- (c.) If an agency does not practice drug testing of its employees, the written policy must state that the agency does not conduct drug testing of its employees.
- (d.) An agency must provide a copy of the policy to anyone applying for services from the agency and any person who requests it.

§558.254 Billing and Insurance Claims

The agency must adopt and enforce a written policy to ensure that the agency submits accurate billings and insurance claims.

§558.255 Prohibition of Solicitation of Patients

- (a.) An agency must adopt and enforce a written policy to ensure compliance of the agency and its employees and contractors with Texas Occupations Code Chapter 102. For the purpose of this section, a patient is considered to be a client.
- (b.) HHSC may take enforcement action against an agency in accordance with §558.601 of this chapter (relating to Enforcement Actions) and §558.602 of this chapter (relating to Administrative Penalties), if the agency violates Texas Occupations Code §102.001, Soliciting Patients; Offense or §102.006, Failure to Disclose; Offense.

§558.256 Emergency Preparedness Planning and Implementation

- (a) An agency must have a written emergency preparedness and response plan that comprehensively describes its approach to a disaster that could affect the need for its services or its ability to provide those services. The written plan must be based on a risk assessment that identifies the disasters from natural and man-made causes that are likely to occur in the agency's service area. Except for a freestanding hospice inpatient unit, HHSC does not require an agency to physically evacuate or transport a client.
- (b) Agency personnel that must be involved with developing, maintaining, and implementing an agency's emergency preparedness and response plan include:
 - (1.) the administrator;
 - (2.) the supervising nurse, if the agency is required to employ or contract with a supervising nurse, as required by §558.243 of this subchapter (relating to Administrative and Supervisory Responsibilities);
 - (3.) the agency disaster coordinator; and
 - (4.) the alternate disaster coordinator.
- (c) An agency's written emergency preparedness and response plan must:
 - (1.) designate, by title, an employee, and at least one alternate employee, to act as the agency's disaster coordinator;
 - (2.) include a continuity of operations business plan that addresses emergency financial needs, essential functions for client services, critical personnel, and how to return to normal operations as quickly as possible;

- (3.)include how the agency will monitor disaster-related news and information, including after hours, weekends, and holidays, to receive warnings of imminent and occurring disasters;
 - (4.)include procedures to release client information in the event of a disaster, in accordance with the agency's written policy required by §558.301(a)(2) of this subchapter (relating to Client Records); and
 - (5.)describe the actions and responsibilities of agency staff in each phase of emergency planning, including mitigation, preparedness, response, and recovery.
- (d) The response and recovery phases of the plan must describe:
- (1.)the actions and responsibilities of agency staff when warning of an emergency is not provided;
 - (2.)who at the agency will initiate each phase;
 - (3.)a primary mode of communication and alternate communication or alert systems in the event of telephone or power failure; and
 - (4.)procedures for communicating with:
 - (A) staff;
 - (B) clients or persons responsible for a client's emergency response plan;
 - (C) local, state, and federal emergency management agencies; and
 - (D) other entities including HHSC and other health care providers and suppliers.
- (e) An agency's emergency preparedness and response plan must include procedures to triage clients that allow the agency to:
- (1.)readily access recorded information about an active client's triage category in the event of an emergency to implement the agency's response and recovery phases, as described in subsection (d) of this section; and
 - (2.)categorize clients into groups based on:
 - (A) the services the agency provides to a client;
 - (B) the client's need for continuity of the services the agency provides; and
 - (C) the availability of someone to assume responsibility for a client's emergency response plan, if needed by the client.
- (f) The agency's emergency preparedness and response plan must include procedures to identify a client who may need evacuation assistance from local or state jurisdictions because the client:
- (1.)cannot provide or arrange for his or her transportation; or
 - (2.)has special health care needs requiring special transportation assistance.

- (g) If the agency identifies a client who may need evacuation assistance, as described in subsection (f) of this section, agency personnel must provide the client with the amount of assistance the client requests to complete the registration process for evacuation assistance, if the client:
 - (1.)wants to register with the State of Texas Emergency Assistance Registry (STEAR), accessed by dialing 2-1-1; and
 - (2.)is not already registered, as reported by the client or legally authorized representative.
- (h) An agency must provide and discuss the following information about emergency preparedness with each client:
 - (1.)the actions and responsibilities of agency staff during and immediately following an emergency;
 - (2.)the client's responsibilities in the agency's emergency preparedness and response plan;
 - (3.)materials that describe survival tips and plans for evacuation and sheltering in place; and
 - (4.)a list of community disaster resources that may assist a client during a disaster, including the STEAR, for which registration is available through 2-1-1 Texas, and other community disaster resources provided by local, state, and federal emergency management agencies. An agency's list of community disaster resources must include information on how to contact the resources directly or instructions to call 2-1-1 for more information about community disaster resources.
- (i) An agency must orient and train employees, volunteers, and contractors about their responsibilities in the agency's emergency preparedness and response plan.
- (j) An agency must complete an internal review of the plan at least annually, and after each actual emergency response, to evaluate its effectiveness and to update the plan as needed.
- (k) As part of the annual internal review, an agency must test the response phase of its emergency preparedness and response plan in a planned drill, if not tested during an actual emergency response. Except for a freestanding hospice inpatient unit, a planned drill can be limited to the agency's procedures for communicating with staff.
- (l) An agency must make a good faith effort to comply with the requirements of this section during a disaster. If the agency is unable to comply with any of the requirements of this section, it must document in the agency's records attempts of staff to follow procedures outlined in the agency's emergency preparedness and response plan.
- (m)An agency is not required to continue to provide care to clients in emergency situations that are beyond the agency's control and that make it impossible to provide services, such as when roads are impassable or when a client relocates to a place unknown to the agency. An agency may establish links to local emergency operations centers to determine a mechanism by which to approach specific areas within a disaster area for the agency to reach its clients.

- (n) If written records are damaged during a disaster, the agency must not reproduce or recreate client records, except from existing electronic records. Records reproduced from existing electronic records must include:
 - (1.)the date the record was reproduced;
 - (2.)the agency staff member who reproduced the record; and
 - (3.)how the original record was damaged.
- (o) Notwithstanding the provisions specified in Division 2 of this subchapter (relating to Conditions of a License), no later than five working days after an agency temporarily relocates a place of business, or temporarily expands its service area resulting from the effects of an emergency or disaster, an agency must notify and provide the following information to the HHSC Home and Community Support Services Agencies licensing unit:
 - (1.)if temporarily relocating a place of business:
 - (A) the license number for the place of business and the date of relocation;
 - (B) the physical address and phone number of the location; and
 - (C) the date the agency returns to a place of business after the relocation; or
 - (2.)if temporarily expanding the service area to provide services during a disaster:
 - (A) the license number and revised boundaries of the service area;
 - (B) the date the expansion begins; and
 - (C) the date the expansion ends.
- (p) An agency must provide the notice and information described in subsection (o) of this section by fax or email. If fax and email are unavailable, the agency may notify the HHSC licensing unit by telephone but must provide the notice and information in writing as soon as possible. If communication with the HHSC licensing unit is not possible, the agency must provide the notice and information by fax, email, or telephone to the designated survey office.
- (q) Emergency Response System.
 - (1.)The agency administrator and alternate administrator must enroll in an emergency communication system in accordance with instructions from HHSC.
 - (2.)The agency must respond to requests for information received through the emergency communication system in the format established by HHSC.

§558.257 Medicare Certification Optional

- (a.) An agency that applies for the category of licensed and certified home health services must comply with the regulations in, the Medicare Conditions of Participation for Home Health Agencies, 42 CFR Part 484, pending approval of certification granted by CMS. After HHSC receives written approval from CMS, HHSC amends the licensing status of the agency to include the licensed and certified home health services category.

- (b.) An agency providing hospice services and applying for participation in the Medicare program must comply with the Medicare Conditions of Participation for Hospice Care, 42 CFR Part 418, pending approval of certification granted by CMS. After HHSC receives written approval from CMS, HHSC enters the hospice provider number issued by CMS into its Home and Community Support Services Agencies database but does not amend the hospice services category on the license.

§558.259 Initial Educational Training in Administration of Agencies

- (a.) This section applies only to an administrator and alternate administrator designated as an administrator or alternate administrator for the first time on or after December 1, 2006.
- (b.) In addition to the qualifications and conditions described in §558.244 of this division (relating to Administrator Qualifications and Conditions and Supervising Nurse Qualifications), a first-time administrator and alternate administrator of an agency must each complete a total of 24 clock hours of educational training in the administration of an agency before the end of the first 12 months after designation to the position.
- (c.) Prior to designation, a first-time administrator or alternate administrator must complete eight clock hours of educational training in the administration of an agency. The initial eight clock hours must be completed during the 12 months immediately preceding the date of designation to the position. The initial eight clock hours must include:
 - (1.) information on the licensing standards for an agency; and
 - (2.) information on the state and federal laws applicable to an agency, including:
 - (A) Texas Health and Safety Code Chapters 142 and 250.
 - (B) Texas Human Resources Code Chapter 102, Rights of the Elderly;
 - (C) the Americans with Disabilities Act;
 - (D) the Civil Rights Act of 1991;
 - (E) the Rehabilitation Act of 1993;
 - (F) the Family and Medical Leave Act of 1993; and
 - (G) the Occupational Safety and Health Administration requirements.
- (d.) A first-time administrator and alternate administrator must complete an additional 16 clock hours of educational training before the end of the first 12 months after designation to the position. Any of the additional 16 clock hours may be completed prior to designation, if completed during the 12 months immediately preceding the date of designation to the position. The additional 16 clock hours must include the following subjects and may include other topics related to the duties of an administrator:
 - (1.) information regarding fraud and abuse detection and prevention;
 - (2.) legal issues regarding advance directives;
 - (3.) client rights, including the right to confidentiality;
 - (4.) agency responsibilities;
 - (5.) complaint investigation and resolution;

- (6.) emergency preparedness planning and implementation;
 - (7.) abuse, neglect, and exploitation;
 - (8.) infection control;
 - (9.) nutrition (for agencies licensed to provide inpatient hospice services); and
 - (10.) the Outcome and Assessment Information Set (OASIS) (for agencies licensed to provide licensed and certified home health services).
- (e.) The 24-hour educational training requirement described in subsection (b) of this section must be met through structured, formalized classes, correspondence courses, competency-based computer courses, training videos, distance learning programs, or off-site training courses. Subject matter that deals with the internal affairs of an organization does not qualify for credit.
- (1.) The training must be provided or produced by:
 - (A) an academic institution;
 - (B) a recognized state or national organization or association;
 - (C) an independent contractor who consults with agencies; or
 - (D) an agency.
 - (2.) If an agency or independent contractor provides or produces the training, the training must be approved by HHSC or recognized by a state or national organization or association. The agency must maintain documentation of this approval or recognition for review by HHSC surveyors.
 - (3.) A first-time administrator and alternate administrator may apply joint training provided by HHSC toward the 24 hours of educational training required by this section if the joint training meets the educational training requirements described in subsections (c) and (d) of this section.
- (f.) Documentation of administrator and alternate administrator training must:
- (1.) be on file at the agency; and
 - (2.) contain the name of the class or workshop, the course content (such as the curriculum), the hours and dates of the training, and the name and contact information of the entity and trainer who provided the training.
- (g.) A first-time administrator and alternate administrator must not apply the HHSC Presurvey Training toward the 24 hours of educational training required in this section.
- (h.) After completing the 24 hours of initial educational training prior to or during the first 12 months after designation as a first-time administrator and alternate administrator, an administrator and alternate administrator must complete the continuing education requirements as specified in §558.260 of this division (relating to Continuing Education in Administration of Agencies) in each subsequent 12-month period after designation.

§558.260 Continuing Education in Administration of Agencies

- (a.) In addition to the qualifications and conditions described in §558.244 of this division (relating to Administrator Qualifications and Conditions and Supervising Nurse Qualifications), an administrator and alternate administrator must complete 12 clock hours of continuing education within each 12-month period beginning with the date of designation. The 12 clock hours of continuing education must include at least two of the following topics and may include other topics related to the duties of an administrator:
- (1.) any one of the educational training subjects listed in §558.259(d) of this division (relating to Initial Educational Training in Administration of Agencies);
 - (2.) development and interpretation of agency policies;
 - (3.) basic principles of management in a licensed health-related setting;
 - (4.) ethics;
 - (5.) quality improvement;
 - (6.) risk assessment and management;
 - (7.) financial management;
 - (8.) skills for working with clients, families, and other professional service providers;
 - (9.) community resources; or
 - (10.) marketing.
- (b.) This subsection applies only to an agency administrator or alternate administrator designated as an agency administrator or alternate administrator before December 1, 2006, who has not served as an administrator or alternate administrator for 180 days or more immediately preceding the date of designation. Within the first 12 months after the date of designation, at least eight of the 12 clock hours of continuing education must include the topics listed in §558.259(c) of this division. The remaining four hours of continuing education must include topics related to the duties of an administrator and may include the topics listed in subsection (a) of this section.
- (c.) Documentation of administrator and alternate administrator continuing education must:
- (1.) be on file at the agency; and
 - (2.) contain the name of the class or workshop, the topics covered, and the hours and dates of the training.
- (d.) An administrator or alternate administrator must not apply the HHSC Presurvey Training toward the continuing education requirements in this section.

Division 4 Provision and Coordination of Treatment Services

§558.281 Client Care Policies

An agency must adopt and enforce a written policy that specifies the agency's client care practices. The written policy must include the following elements if covered under the scope of services provided by the agency:

- (1.) initial assessment, reassessment;

- (2.) start of care, placing services on hold, transfer, and discharge;
- (3.) intravenous services;
- (4.) care of the pediatric client;
- (5.) triaging clients in the event of disaster;
- (6.) how to handle emergencies in the home;
- (7.) safety of staff;
- (8.) procedures the staff will perform for clients, such as dressing changes, Foley catheter changes, wound irrigation, administration of medication;
- (9.) psychiatric nursing procedures;
- (10.) patient and caregiver teaching relating to disease process/procedures;
- (11.) care planning;
- (12.) care of a client who has a terminal illness or a terminal prognosis;
- (13.) receiving physician orders;
- (14.) performing waived testing;
- (15.) medication monitoring; and
- (16.) anything else pertaining to client care.

§558.282 Client Conduct and Responsibility and Client Rights

- (a.) An agency must adopt and enforce a written policy governing client conduct and responsibility and client rights, in accordance with this section. The written policy must include a grievance mechanism under which a client can participate without fear of reprisal.
- (b.) An agency must protect and promote the rights of all clients.
- (c.) An agency must comply with the provisions of the Texas Human Resources Code Chapter 102, which applies to a client 60 years of age or older.
- (d.) At the time of admission, an agency must provide a client who receives licensed home health services, licensed and certified home health services, hospice services, or personal assistance services, with a written statement that informs the client that a complaint against the agency may be directed to HHSC Complaint and Incident Intake, P.O. Box 149030, Austin, Texas 78714-9030, toll free 1-800-458-9858. The statement also may inform the client that a complaint against the agency may be directed to the administrator of the agency. The statement about complaints directed to the administrator also must include the time frame in which the agency reviews and resolves a complaint.
- (e.) In advance of furnishing care to a client, or during the initial evaluation visit before the initiation of treatment, an agency must provide the client, or their legal representative, with a written notice of all policies governing client conduct and responsibility and client rights.
- (f.) A client has the following rights:

- (1.) A client has the right to be informed in advance about the care to be furnished, the plan of care, expected outcomes, barriers to treatment, and any changes in the care to be furnished. The agency must ensure that written informed consent, specifying the type of care and services that may be provided by the agency, has been obtained for every client, either from the client or their legal representative. The client or the legal representative must sign or mark the consent form.
- (2.) A client has the right to participate in planning the care or treatment and in planning a change in the care or treatment.
 - (A) An agency must advise or consult with the client or legal representative in advance of any change in the care or treatment.
 - (B) A client has the right to refuse care and services.
 - (C) A client has the right to be informed, before care is initiated, of the extent to which payment may be expected from the client, a third-party payer, and any other source of funding known to the agency.
- (3.) A client has the right to have assistance in understanding and exercising the client's rights. The agency must maintain documentation showing that it has complied with the requirements of this paragraph and that the client demonstrates understanding of the client's rights.
- (4.) A client has the right to exercise rights as a client of the agency.
- (5.) A client has the right to have the client's person and property treated with consideration, respect, and full recognition of the client's individuality and personal needs.
- (6.) A client has the right to be free from abuse, neglect, and exploitation by an agency employee, volunteer, or contractor.
- (7.) A client has the right to confidential treatment of the client's personal and medical records.
- (8.) A client has the right to voice grievances regarding treatment or care that is, or fails to be, furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the agency, and they must not be subjected to discrimination or reprisal for doing so.
- (g.) In the case of a client adjudged incompetent, the rights of the client are exercised by the person appointed by law to act on the client's behalf.
- (h.) In the case of a client who has not been adjudged incompetent, any legal representative may exercise the client's rights to the extent permitted by law.

§558.283 Advance Directives

- (a.) An agency must maintain a written policy regarding implementation of advance directives. The policy must comply with the Advance Directives Act, Texas Health and Safety Code Chapter 166. The policy must include a clear and precise statement of any procedure the agency is unwilling or unable to provide or withhold in accordance with an advance directive.

- (b.) The agency must provide written notice to a client of the written policy required by subsection (a) of this section. The notice must be provided at the earlier of:
 - (1.) the time the client is admitted to receive services from the agency; or
 - (2.) the time the agency begins providing care to the client.
- (c.) If, at the time notice must be provided under subsection (b) of this section, the client is incompetent or otherwise incapacitated and unable to receive the notice, the agency must provide the required written notice, in the following order of preference, to:
 - (1.) the client's legal guardian;
 - (2.) a person responsible for the health care decisions of the client;
 - (3.) the client's spouse;
 - (4.) the client's adult child;
 - (5.) the client's parent; or
 - (6.) the person admitting the client.
- (d.) If subsection (c) of this section applies, except as provided by subsection (e) of this section, and an agency is unable, after a diligent search, to locate an individual listed by subsection (c) of this section, the agency is not required to provide the notice.
- (e.) If a client who was incompetent or otherwise incapacitated and unable to receive the notice required by this section, at the time notice was to be provided under subsection (b) of this section, later becomes able to receive the notice, the agency must provide the written notice at the time the client becomes able to receive the notice.
- (f.) HHSC assesses an administrative penalty of \$500 without an opportunity to correct against an agency that violates this section.

§558.284 Laboratory Services

An agency that provides laboratory services must adopt and enforce a written policy to ensure that the agency meets applicable requirements of 42 United States Code (USC) §263a, concerning certification and certificates of waiver of a clinical laboratory (CLIA 1988). The section 42 USC §263a applies to all agencies with laboratories that examine human specimens to provide information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

§558.285 Infection Control

An agency must adopt and enforce written policies addressing infection control, including the prevention of the spread of infectious and communicable disease. The policies must:

- (1.) ensure compliance by the agency, its employees, and its contractors with:
 - (A) Texas Health and Safety Code Chapter 81, relating to prevention and control of communicable diseases;
 - (B) Occupational Safety and Health Administration regulations relating to Bloodborne Pathogens at, 29 CFR Part 1910.1030, and Appendix A to that section; and

- (C) Texas Health and Safety Code Chapter 85, Subchapter I, concerning the prevention of the transmission of human immunodeficiency virus and hepatitis B virus; and
- (2.) require documentation of infections that the client acquires while receiving services from the agency.
 - (A) If an agency is licensed to provide services other than personal assistance services, documentation must include the date that the infection was detected, the client's name, primary diagnosis, signs and symptoms, type of infection, pathogens identified, and treatment.
 - (B) If an agency is licensed to provide only personal assistance services, documentation must include the date that the infection was disclosed to the agency employee, the client's name, and treatment as disclosed by the client.

§558.286 Disposal of Special or Medical Waste

- (a.) An agency must adopt and enforce a written policy for the safe handling and disposal of biohazardous waste and materials, if applicable.
- (b.) An agency that generates special or medical waste while providing home health services must dispose of the waste according to the requirements in 25 TAC Chapter 1, Subchapter K (relating to Definition, Treatment, and Disposition of Special Waste from Health Care-Related Facilities). An agency must provide both verbal and written instructions to the agency's clients regarding the proper procedure for disposing of sharps. For purposes of this subsection, sharps include hypodermic needles, hypodermic syringes with attached needles, scalpel blades, razor blades, disposable razors, disposable scissors used in medical procedures, and intravenous stylets and rigid introducers.

§558.287 Quality Assessment and Performance Improvement

- (a.) Quality Assessment and Performance Improvement (QAPI) Program.
 - (1.) An agency must maintain a QAPI Program that is implemented by a QAPI Committee. The QAPI Program must be ongoing, focused on client outcomes that are measurable, and have a written plan of implementation. The QAPI Committee must review and update or revise the plan of implementation at least once within a calendar year, or more often if needed. The QAPI Program must include:
 - (A) a system that measures significant outcomes for optimal care. The QAPI Committee must use the measures in the care planning and coordination of services and events. The measures must include the following as appropriate for the scope of services provided by the agency:
 - (i) an analysis of a representative sample of services furnished to clients contained in both active and closed records;
 - (ii) a review of:
 - I. negative client care outcomes;
 - II. complaints and incidents of unprofessional conduct by licensed staff and misconduct by unlicensed staff;

- III. infection control activities;
- IV. medication administration and errors; and
- V. effectiveness and safety of all services provided, including:
 - a. the competency of the agency's clinical staff;
 - b. the promptness of service delivery; and
 - c. the appropriateness of the agency's responses to client complaints and incidents;
- (iii) a determination that services have been performed as outlined in the individualized service plan, care plan, or plan of care; and
- (iv) an analysis of client complaint and satisfaction survey data; and
- (B) an annual evaluation of the total operation, including services provided under contract or arrangement.
 - (i) An agency must use the evaluation to correct identified problems and, if necessary, to revise policies.
 - (ii) An agency must document corrective action to ensure that improvements are sustained over time.
- (2.) An agency must immediately correct identified problems that directly or potentially threaten the client care and safety.
- (3.) QAPI documents must be kept confidential and be made available to HHSC staff upon request.
- (b.) QAPI Committee membership. At a minimum, the QAPI Committee must consist of:
 - (1.) the administrator;
 - (2.) the supervising nurse or therapist, or the supervisor of an agency licensed to provide personal assistance services; and
 - (3.) an individual representing the scope of services provided by the agency.
- (c.) Frequency of QAPI Committee meeting. The QAPI Committee must meet twice a year or more often if needed.

§558.288 Coordination of Services

- (a.) An agency must adopt and enforce a written policy regarding coordination of services to ensure the effective exchange of information, reporting, and coordination of client services among:
 - (1.) all agency personnel providing care and services, whether the care and services are provided directly or under arrangement;
 - (2.) the agency and other providers of health care services involved in the care of a client, if known by the agency; and
 - (3.) the agency and a licensed facility, group home, foster home, or boarding home facility in which a client resides.

- (b.) The agency must include documentation in the client record of coordination of services as specified in subsection (a) of this section.
- (c.) In this section, other providers of health care services involved in the care of a client may include:
 - (1.) a physician;
 - (2.) another agency;
 - (3.) an adult day care center;
 - (4.) an outpatient facility; and
 - (5.) a managed care organization.

§558.289 Independent Contractors and Arranged Services

- (a.) Independent contractors. If an agency uses independent contractors, there must be a contract between each independent contractor that performs services and the agency. The contract must be enforced by the agency and clearly designate:
 - (1.) that clients are accepted for care only by the agency;
 - (2.) the services to be provided by the contractor and how they will be provided (i.e. per visit, per hours, etc.);
 - (3.) the necessity of the contractor to conform to all applicable agency policies, including personnel qualifications;
 - (4.) the contractor's responsibility for participating in developing the plan of care, care plan, or individualized service plan;
 - (5.) the way services will be coordinated and evaluated by the agency in accordance with §558.288 of this division (relating to Coordination of Services);
 - (6.) the procedures for:
 - (A) submitting information and documentation by the contractor, in accordance with the agency's client record policies;
 - (B) scheduling of visits by the contractor or the agency;
 - (C) periodic client evaluation by the contractor; and
 - (D) determining charges and reimbursement payable by the agency for the contractor's services under the contract.
- (b.) Arranged services. Home health services, hospice services, or personal assistance services provided by an agency under arrangement with another agency or organization must be provided under a written contract conforming to the requirements specified in subsection (a) of this section.
- (c.) If an agency contracts with another agency or organization for an unlicensed person to provide home health services, hospice services, or personal assistance services under arrangement, the agency must ensure that either it or the contracting agency or organization:

- (1.) searches the nurse aide registry (NAR) and the employee misconduct registry (EMR) before the unlicensed person's first face-to-face contact with a client of the agency, using the HHSC Internet website to confirm that the unlicensed person is not listed in either registry as unemployable;
 - (2.) provides written information to the unlicensed person about the EMR that complies with the requirements of 40 TAC §93.3(c) (relating to Employment and Registry Information); and
 - (3.) searches the NAR and the EMR at least every 12 months using the HHSC Internet website to confirm that the person is not listed in either registry as unemployable.
- (d.) If an agency contracts with another agency or organization for an unlicensed person to provide home health services, hospice services, or personal assistance services under arrangement, the agency must ensure that the contracting agency or organization:
- (1.) conducts a criminal history check before the unlicensed person's first face-to-face contact with a client of the agency; and
 - (2.) verifies that the unlicensed person's criminal history information does not include a conviction that bars employment under Texas Health and Safety Code §250.006.
- (e.) Documentation for contract staff. An agency is not required to maintain a personnel record for independent contractors or staff who provide services under arrangement with another agency or organization. Upon request by HHSC, an agency must provide documentation at the site of a survey within eight working hours of the request to demonstrate that:
- (1.) independent contractors or staff under arrangement meet the agency's written job qualifications for the position and duties performed;
 - (2.) the agency ensures compliance with subsection (c) of this section for unlicensed staff providing services to the agency's clients under arrangement; and
 - (3.) the agency complies with subsection (d) of this section for unlicensed staff providing services to the agency's clients under arrangement by providing a written statement, signed by a person authorized to make decisions on personnel matters for the contracting agency or organization, attesting that a criminal history check was conducted before an unlicensed person's first face-to-face contact with a client, and did not include a conviction barring employment under Texas Health and Safety Code §250.006.

§558.290 Backup Services and After Hours Care

- (a.) Backup services. An agency must adopt and enforce a written policy to ensure that backup services are available when an agency employee or contractor is not available to deliver the services.
- (1.) Backup services may be provided by an agency employee, a contractor, or the client's designee who is willing and able to provide the necessary services.

- (2.) If the client's designee has agreed to provide backup services required by this section, the agency must have the designee sign a written agreement to be the backup service provider. The agency must keep the agreement in the client's file.
- (3.) An agency must not coerce a client to accept backup services.
- (b.) After-hours care. An agency must adopt and enforce a written policy to ensure that clients are educated in how to access care from the agency or another health care provider after regular business hours.

§558.291 Agency Dissolution

An agency must adopt and enforce a written policy that describes the agency's written contingency plan.

- (1.) The plan must be implemented in the event of dissolution to assure continuity of client care.
- (2.) The plan must:
 - (A) be consistent with §558.295 of this division (relating to Client Transfer or Discharge Notification Requirements);
 - (B) include procedures for:
 - i. notifying the client of the agency's dissolution;
 - ii. documenting the notification;
 - iii. carrying out the notification; and
 - (C) comply with §558.217(a)(2) of this subchapter (relating to Agency Closure Procedures and Voluntary Suspension of Operations).

§558.292 Agency and Client Agreement and Disclosure

- (a.) The agency must provide the client or the client's family with a written agreement for services. The agency must comply with the terms of the agreement. The agreement must include at a minimum the following:
 - (1.) notification of client rights;
 - (2.) documentation concerning notification to the client of the availability of medical power of attorney for health care, advance directive or "Do Not Resuscitate" orders in accordance with the applicable law;
 - (3.) services to be provided;
 - (4.) supervision by the agency of services provided;
 - (5.) agency charges for services rendered if the charges will be paid in full or in part by the client or the client's family, or on request;
 - (6.) a written statement containing procedures for filing a complaint in accordance with §558.282(d) of this division (relating to Client Conduct and Responsibility and Client Rights); and

- (7.) a client agreement to and acknowledgement of services by home health medication aides, if home health medication aides are used.
- (b.) The agency must obtain an acknowledgment of receipt from the client or his family of the items listed under subsection (a) of this section. This acknowledgment of receipt must be kept in the client's record.

§558.293 Client List and Services

An agency must maintain a current list of clients for each category of service licensed.

- (1.) The list must include all services being delivered by the agency and services being delivered under contract.
- (2.) The client list must include the client's name, identification or clinical record number, start of care date or admission date, certification period (if applicable), diagnosis(es) or functional assessment (as appropriate), and the disciplines that are providing services.

§558.294 Time Frame(s) for the Initiation of Care or Services

An agency must adopt and enforce a written policy establishing time frame(s) for the initiation of care or services.

§558.295 Client Transfer or Discharge Notification Requirements

- (a.) Except as provided in subsection (e) of this section, an agency intending to transfer or discharge a client must:
 - (1.) provide written notification to the client or the client's parent, family, spouse, significant other, or legal representative; and
 - (2.) notify the client's attending physician or practitioner if he is involved in the agency's care of the client.
- (b.) An agency must ensure delivery of the written notification no later than five days before the date on which the client will be transferred or discharged.
- (c.) The agency must deliver the required notice by hand or by mail.
- (d.) If the agency delivers the written notice by mail:
 - (1.) the notice must be mailed at least eight working days before the date of transfer or discharge; and
 - (2.) the agency must speak with the client by telephone or in person to ensure the client's knowledge of the transfer or discharge, at least five days before the date of transfer or discharge.
- (e.) An agency may transfer or discharge a client without prior notice required by subsection (b) of this section:
 - (1.) upon the client's request;
 - (2.) if the client's medical needs require transfer, such as a medical emergency;
 - (3.) in the event of a disaster when the client's health and safety is at risk, in accordance with provisions of §558.256 of this subchapter (relating to Emergency Preparedness Planning and Implementation);

- (4.)for the protection of staff or a client after the agency has made a documented reasonable effort to notify the client, the client's family and physician, and appropriate state or local authorities, of the agency's concerns for staff or client safety, and in accordance with agency policy;
 - (5.)according to physician orders; or
 - (6.)if the client fails to pay for services, except as prohibited by federal law.
- (f.) An agency must keep the following in the client's file:
- (1.)a copy of the written notification provided to the client or the client's parent, family, spouse, significant other, or legal representative;
 - (2.)documentation of the personal contact with the client, if the required notice was delivered by mail; and
 - (3.)documentation that the client's attending physician or practitioner was notified of the date of discharge.

§558.296 Physician Delegation and Performance of Physician-Delegated Tasks

- (a.) An agency must adopt and enforce a written policy that states whether physician delegation will be honored by the agency. If an agency accepts physician delegation, the agency must comply with Texas Occupations Code Chapter 157, concerning physician delegation.
- (b.)An agency may accept delegation from a physician only if the agency receives the following from the physician:
- (1.)the name of the client;
 - (2.)the name of the delegating physician;
 - (3.)the task(s) to be performed;
 - (4.)the name of the individual(s) to perform the task(s);
 - (5.)the time frame for the delegation order; and
 - (6.)if the task is medication administration, the medication to be given, route, dose, and frequency.

§558.297 Receipt of Physician Orders

An agency must adopt and enforce a written policy describing protocols and procedures agency staff must follow when receiving physician orders.

- (1.)The policy must address the time frame for countersignature of physician verbal orders.
- (2.)Signed physician orders may be submitted via fax machine. The agency is not required to have the original signatures on file. However, the agency must be able to obtain original signatures if an issue surfaces that would require verification of an original signature. The policy must include protocols to follow when accepting physician orders via fax. If physician orders are accepted via fax, the policy must:
 - (A)outline safeguards to assure that transmitted information is sent to the appropriate individual; and

(B) outline the procedures to be followed in the case of misdirected transmission.

§558.298 Delegation of Nursing Tasks by Registered Professional Nurses to Unlicensed Personnel and Tasks Not Requiring Delegation

- (a.) An agency must adopt and enforce a written policy to ensure compliance with the following rules adopted by the Texas Board of Nursing:
 - (1.) 22 TAC Chapter 224 (relating to Delegation of Nursing Tasks by Registered Professional Nurses to Unlicensed Personnel for Clients with Acute Conditions or in Acute Care Environments); and
 - (2.) 22 TAC Chapter 225 (relating to RN Delegation to Unlicensed Personnel and Tasks Not Requiring Delegation in Independent Living Environments for Clients with Stable and Predictable Conditions).
- (b.) Requirements for RN delegation for personal assistance service clients are located in §558.404 of this chapter (relating to Standards Specific to Agencies Licensed to Provide Personal Assistance Services).

§558.299 Nursing Education, Licensure and Practice

If providing nursing services, an agency must adopt and enforce a written policy to ensure compliance with the rules of the Texas Board of Nursing adopted in 22 TAC Chapters 211 - 226 (relating to Nursing Continuing Education, Licensure, and Practice in the State of Texas).

§558.300 Medication Administration

- (a.) This section applies only to clients to whom agency staff administer medications.
- (b.) An agency must adopt and enforce a written policy for maintaining a current medication list and a current medication administration record.
 - (1.) A client's practitioner must order administration of medication.
 - (2.) An agency may incorporate a current medication list and medication administration record into one document.
 - (A) An agency must use the medication list to identify possible ineffective drug therapy or adverse reactions, significant side effects, drug allergies, and contraindications.
 - (B) An agency must document in the medication administration record or clinical notes any medication that is not administered and the reason it was not administered.
 - (3.) An individual delivering care must report any adverse reaction to a supervisor and document this in the client's record on the day of occurrence. If the adverse reaction occurs after regular business hours, the individual delivering care must report the adverse reaction as soon as it is disclosed.

§558.301 Client Records

(a.) In accordance with accepted principles of practice, an agency must establish and maintain a client record system to ensure that the care and services provided to each client are completely and accurately documented, readily accessible, and systematically organized to facilitate the compilation and retrieval of information.

- (1.) An agency must establish a record for each client and must maintain the record in accordance with and contain the information described in paragraph (9) of this subsection. An agency must keep a single file or separate files for each category of service provided to the client and the client's family. Hospice services provided to a client's family must be documented in the clinical record.
- (2.) The agency must adopt and enforce written procedures regarding the use and removal of records, the release of information, and when applicable, the incorporation of clinical, progress, or other notes into the client record. An agency may not release any portion of a client record to anyone other than the client except as allowed by law.
- (3.) All information regarding the client's care and services must be centralized in the client's record and be protected against loss or damage.
- (4.) The agency must establish an area for original active client record storage at the agency's place of business. The original active client record must be stored at the place of business (parent agency, branch office, or ADS) from which services are provided. Original active client records must not be stored at an administrative support site or records storage facility.
- (5.) The agency must ensure that each client's record is treated with confidentiality, safeguarded against loss and unofficial use, and is maintained according to professional standards of practice.
- (6.) A clinical record must be an original, a microfilmed copy, an optical disc imaging system, or a certified copy.

(A) An original record is a signed paper record or an electronically signed computer record. A signed paper record may include a physician's stamped signature if the agency meets the following requirements:

- (i) An agency must have on file at the agency a current written authorization letter from the physician whose signature the stamp represents, stating that he is the only person authorized to have the stamp and use it.
- (ii) The authorization letter must be dated before a stamped record from the physician was accepted by the agency.
- (iii) An agency must obtain a new authorization letter from the physician annually. A physician authorization letter is void one year from the date of the letter.
- (iv) The authorization letter must be manually signed by the physician and include a copy of the stamped signature that the physician will use.

- (B) Computerized records must meet all requirements of paper records, including protection from unofficial use and retention for the period specified in subsection (b) of this section.
 - (C) An agency must ensure that entries regarding the delivery of care or services are not altered without evidence and explanation of such alteration.
- (7.) Each entry to the client record must be current, accurate, signed, and dated with the date of entry by the individual making the entry. The record must include all services whether furnished directly or under arrangement. Correction fluid or tape must not be used in the record. Corrections must be made by striking through the error with a single line and must include the date the correction was made and the initials of the person making the correction.
- (8.) Inactive client records may be preserved on microfilm, optical disc or other electronic means and may be stored at the parent agency location, branch office, ADS, administrative support site, or records storage facility. Security must be maintained, and the record must be readily retrievable by the agency.
- (9.) Each client record must include the following elements as applicable to the scope of services provided by the agency:
- (A) client application for services including, but not limited to, the following information:
 - (i) the client's full name;
 - (ii) sex;
 - (iii) date of birth;
 - (iv) the name, address, and telephone number of each parent or legal guardian of a minor child;
 - (v) the name, address, and telephone number of any other person; as identified by the individual;
 - (vi) the physician's name and telephone numbers, including emergency numbers; and
 - (vii) services requested;
 - (B) initial health assessment, pertinent medical history, and subsequent health assessments;
 - (C) care plan, plan of care, or individualized service plan, as applicable. The care plan or the plan of care must include, as applicable, medication, dietary, treatment, and activities orders. An individualized service plan for a personal assistance service client must comply with §558.404 of this chapter (relating to Standards Specific to Agencies Licensed to Provide Personal Assistance Services). A plan of care for a hospice client must comply with §558.821 of this chapter (relating to Hospice Plan of Care);

- (D) clinical and progress notes. Such notes must be written the day service is rendered and incorporated into the client record within 14 working days;
- (E) current medication list;
- (F) medication administration record (if medication is administered by agency staff). Notation must also be made in the medication administration record or in the clinical notes of medications not given and the reason. Any adverse reaction must be reported to a supervisor and documented in the client record;
- (G) acknowledgement of hospice agency's policy regarding disposal of controlled substance prescription drugs;
- (H) records of supervisory visits;
- (I) complete documentation of all known services and significant events. Documentation must show that effective interchange, reporting, and coordination of care occurs as required in §558.288 of this division (relating to Coordination of Services);
- (J) for clients 60 years and older, acknowledgment of the client's receipt of a copy of the right and responsibilities listed in Texas Human Resources Code Chapter 102;
- (K) acknowledgment of the client's receipt of the agency's policy relating to the reporting of abuse, neglect, or exploitation of a client;
- (L) documentation that the client has been informed of how to register a complaint in accordance with §558.282(d) of this division (relating to Client Conduct and Responsibility and client Rights);
- (M) client agreement to and acknowledgment of services by home health medication aides, if home health medication aides are used;
- (N) discharge summary, including the reason for discharge or transfer and the agency's documented notice to the client, the client's physician (if applicable), and other individuals as required in §558.295 of this division (relating to Client Transfer or Discharge Notification Requirements);
- (O) acknowledgement of receipt of the notice of advance directives;
- (P) services provided to the client's family (as applicable); and
- (Q) consent and authorization and election forms, as applicable.

(b.) An agency must adopt and enforce a written policy relating to the retention of records in accordance with this subsection.

- (1.) An agency must retain original client records for a minimum of five years after the discharge of the client.
- (2.) The agency may not destroy client records that relate to any matter that is involved in litigation if the agency knows the litigation has not been finally resolved.

- (3.) There must be an arrangement for the preservation of inactive records to insure compliance with this subsection.

§558.302 Pronouncement of Death

An agency must adopt and enforce a written policy on pronouncement of death, if that function is carried out by an agency RN. The policy must comply with Texas Health and Safety Code §671.001 (relating to Standard Used in Determining Death).

§558.303 Standards for Possession of Sterile Water or Saline, Certain Vaccines or Tuberculin, and Certain Dangerous Drugs

An agency that possesses sterile water or saline, certain vaccines or tuberculin, or certain dangerous drugs, as specified by this section, must comply with the provisions of this section.

- (1.) Possession of sterile water or saline. An agency or its employees, who are RNs or LVNs, may purchase, store, or transport for the purpose of administering to their home health or hospice clients under physician's orders:

- (A) sterile water for injection and irrigation; and
- (B) sterile saline for injection and irrigation.

- (2.) Possession of certain vaccines or tuberculin.

- (A) An agency or its employees, who are RNs or LVNs, may purchase, store, or transport for administering to the agency's employees, home health or hospice clients, or client family and household members under physician's standing orders the following dangerous drugs:

- (i) hepatitis B vaccine;
- (ii) influenza vaccine;
- (iii) tuberculin purified protein derivative for tuberculosis testing;
- (iv) pneumococcal polysaccharide vaccine; and
- (v) any other vaccine approved, authorized for emergency use, or otherwise permitted for use by the United States Food and Drug Administration to treat or mitigate the spread of a communicable disease, as defined by Texas Health and Safety Code §81.003.

- (B) An agency that purchases, stores, or transports a vaccine or tuberculin under this section must ensure that any standing order for the vaccine or tuberculin:

- (i) is signed and dated by the physician;
- (ii) identifies the vaccine or tuberculin covered by the order;
- (iii) indicates that the recipient of the vaccine or tuberculin has been assessed as an appropriate candidate to receive the vaccine or tuberculin and has been assessed for the absence of any contraindication;

- (iv) indicates that appropriate procedures are established for responding to any negative reaction to the vaccine or tuberculin; and
- (v) orders that a specific medication or category of medication be administered if the recipient has a negative reaction to the vaccine or tuberculin.

(C) An agency or the agency's authorized employees may purchase, store, or transport vaccines or tuberculin in a sealed portable container only if the agency has established policies and procedures to ensure that:

- (i) the container is handled properly with respect to storage, transportation, and temperature stability according to manufacturer's instructions; and
- (ii) the agency adheres to guidance from the Centers for Disease Control and Prevention and the Texas Health and Human Services Commission.

(3.) Possession of certain dangerous drugs.

(A) In compliance with Texas Health and Safety Code §142.0063, an agency or its employees, who are RNs or LVNs, may purchase, store, or transport for the purpose of administering to their home health or hospice patients, in accordance with subparagraph (C) of this paragraph, the following dangerous drugs:

- (i) any of the following items in a sealed portable container of a size determined by the dispensing pharmacist:
 - I. 1,000 milliliters of 0.9 percent sodium chloride intravenous infusion;
 - II. 1,000 milliliters of 5.0 percent dextrose in water injection; or
 - III. sterile saline; or
- (ii) not more than five dosage units of any of the following items in an individually sealed, unused portable container:
 - I. heparin sodium lock flush in a concentration of 10 units per milliliter or 100 units per milliliter;
 - II. epinephrine HCl solution in a concentration of one to 1,000;
 - III. diphenhydramine HCl solution in a concentration of 50 milligrams per milliliter;
 - IV. methylprednisolone in a concentration of 125 milligrams per two milliliters;
 - V. naloxone in a concentration of one milligram per milliliter in a two-milliliter vial;
 - VI. promethazine in a concentration of 25 milligrams per milliliter;
 - VII. glucagon in a concentration of one milligram per milliliter;

- VIII. furosemide in a concentration of 10 milligrams per milliliter;
- IX. lidocaine 2.5 percent and prilocaine 2.5 percent cream in a five-gram tube; or
- X. lidocaine HCL solution in a concentration of 1 percent in a two-milliliter vial.

(B) An agency or the agency's authorized employees may purchase, store, or transport dangerous drugs in a sealed portable container only if the agency has established policies and procedures to ensure that:

- (i) the container is handled properly with respect to storage, transportation, and temperature stability;
- (ii) a drug is removed from the container only on a physician's written or oral order;
- (iii) the administration of any drug in the container is performed in accordance with a specific treatment protocol; and
- (iv) the agency maintains a written record of the dates and times the container is in the possession of an RN or LVN.

(C) An agency or the agency's authorized employee who administers a drug listed in subparagraph (A) of this paragraph may administer the drug only in the client's residence, under physician's orders, in connection with the provision of emergency treatment or the adjustment of:

- (i) parenteral drug therapy; or
- (ii) vaccine or tuberculin administration.

(D) If an agency or the agency's authorized employee administers a drug listed in subparagraph (A) of this paragraph, pursuant to a physician's oral order, the agency must receive a signed copy of the order:

- (i) not later than 24 hours after receipt of the order, reduce the order to written form and send a copy of the form to the dispensing pharmacy by mail or fax transmission; and
- (ii) not later than 20 days after receipt of the order, send a copy of the order, as signed by and received from the physician, to the dispensing pharmacy.

(E) A pharmacist that dispenses a sealed portable container under this subsection will ensure that the container:

- (i) is designed to allow access to the contents of the container only if a tamper-proof seal is broken;
- (ii) bears a label that lists the drugs in the container and provides notice of the container's expiration date, which is the earlier of:
 - I. the date that is six months after the date on which the container is dispensed; or

- II. the earliest expiration date of any drug in the container; and
 - (iii) remains in the pharmacy or under the control of a pharmacist, RN, or LVN.
- (F) If an agency or the agency's authorized employee purchases, stores, or transports a sealed portable container under this subsection, the agency must deliver the container to the dispensing pharmacy for verification of drug quality, quantity, integrity, and expiration dates not later than the earlier of:
 - (i) the seventh day after the date on which the seal on the container is broken; or
 - (ii) the date for which notice is provided on the container label.
- (G) A pharmacy that dispenses a sealed portable container under this section is required to take reasonable precautionary measures to ensure that the agency receiving the container complies with subparagraph (F) of this paragraph. On receipt of a container under subparagraph (F) of this paragraph, the pharmacy will perform an inventory of the drugs used from the container and will restock and reseal the container before delivering the container to the agency for reuse.

Division 5 Branch Offices and Alternate Delivery Sites

§558.321 Standards for Branch Offices

- (a.) A branch office operates as a part of the parent agency and must comply with the same regulations as the parent agency. The parent agency is responsible for ensuring that its branches comply with licensing standards.
- (b.) A branch office providing licensed and certified home health services must comply with the standards for certified agencies in §558.402 of this chapter (relating to Standards Specific to Licensed and Certified Home Health Services).
- (c.) The service area of a branch office must be located within the parent agency's service area.
 - (1.) A branch office must not provide services outside its licensed service area.
 - (2.) A branch office must maintain adequate staff to provide services and to supervise the provision of services within the service area.
 - (3.) A branch office may expand its service area at any time during the licensure period.
 - (A) Unless exempted under subparagraph (B) of the paragraph, a branch office must submit to HHSC a written notice to expand its service area at least 30 days before the expansion. The notice must include:
 - (i) revised boundaries of the branch office's original service area;
 - (ii) the effective date of the expansion; and
 - (iii) an updated list of management and supervisory personnel (including names), if changes are made.

- (B) An agency is exempt from the 30-day written notice requirement under subparagraph (A) of this paragraph if HHSC determines an emergency exists that would impact client health and safety. An agency must notify HHSC immediately of a possible emergency. HHSC determines if an exemption can be granted.
- (4.) A branch office may reduce its service area at any time during the licensure period by sending HHSC written notification of the reduction, revised boundaries of the branch office's original service area, and the effective date of the reduction.
- (d.) A parent agency and a branch office providing home health or personal assistance services must meet the following requirements:
 - (1.) The parent agency administrator or alternate administrator, or supervising nurse or alternate supervising nurse, must conduct an on-site supervisory visit to the branch office at least monthly. The parent agency may visit the branch office more frequently considering the size of the service area and the scope of services provided by the parent agency. The supervisory visits must be documented and include the date of the visit, the content of the consultation, the individuals in attendance, and the recommendations of the staff.
 - (2.) The original active clinical record must be kept at the branch office.
 - (3.) The parent agency must approve all branch office policies and procedures. This approval must be documented and filed in the parent and branch offices.
- (e.) HHSC issues or renews a branch office license for applicants who meet the requirements of this section.
 - (1.) Issuance or renewal of a branch office license is contingent upon compliance with the Statute and this chapter by the parent agency and branch office.
 - (2.) HHSC may take enforcement action against a parent agency license for a branch office's failure to comply with the Statute or this chapter in accordance with Subchapter F of this chapter (relating to Enforcement).
 - (3.) Revocation, suspension, denial, or surrender of a parent agency license will result in the same revocation, suspension, denial, or surrender of a branch office license for all branch office licenses of the parent agency.
- (f.) A branch office may offer fewer health services or categories than the parent office but may not offer health services or categories that are not also offered by the parent agency.

§558.322 Standards for Alternate Delivery Sites

- (a.) An ADS must comply with the Statute and this chapter, including the additional standards in Subchapter H of this chapter (relating to Standards Specific to Agencies Licensed to Provide Hospice Services).
- (b.) If certified by CMS, an ADS must comply with the applicable federal rules and regulations for hospice agencies in 42 CFR Part 418.
- (c.) A parent agency and an ADS must meet the following requirements:

- (1.) The parent agency administrator or alternate administrator, or supervising nurse or alternate supervising nurse, must conduct an on-site supervisory visit to the ADS at least monthly. The parent agency may visit the ADS more frequently considering the size of the service area provided by the parent agency. The supervisory visits must be documented and include the date of the visit, the content of the consultation, the individuals in attendance, and the recommendations of the staff.
- (2.) The parent agency must approve all ADS policies and procedures. This approval must be documented and filed in the parent agency and ADS.
- (d.) Issuance or renewal of an ADS license is contingent upon compliance by the parent agency and ADS with the Statute and this chapter.
 - (1.) HHSC may take enforcement action against a parent agency license for an ADS' failure to comply with the Statute or this chapter in accordance with Subchapter F of this chapter (relating to Enforcement).
 - (2.) Revocation, suspension, denial or surrender of a parent agency license results in the same revocation, suspension, denial or surrender of all ADS licenses of the parent agency.

Subchapter D, Additional Standards Specific to License Category and Specific to Special Services

§558.401 Standards Specific to Licensed Home Health Services

- (a.) In addition to the standards in Subchapter C of this chapter (relating to Minimum Standards for All Home and Community Support Services Agencies), an agency providing licensed home health services must also meet the standards of this section.
- (b.) The agency must accept a client for home health services based on a reasonable expectation that the client's medical, nursing, and social needs can be met adequately in the client's residence. An agency has made a reasonable expectation that it can meet a client's needs if, at the time of the agency's acceptance of the client, the client and the agency have agreed as to what needs the agency would meet; for instance, the agency and the client could agree that some needs would be met but not necessarily all needs.
 - (1.) The agency must start providing licensed home health services to a client within a reasonable time after acceptance of the client and according to the agency's policy. The initiation of licensed home health services must be based on the client's health service needs.
 - (2.) An initial health assessment must be performed in the client's residence by the appropriate health care professional prior to or at the time that licensed home health services are initially provided to the client. The assessment must determine whether the agency can provide the necessary services.
 - (A) If a practitioner has not ordered skilled care for a client, then the appropriate health care professional must prepare a care plan. The care plan must be developed after consultation with the client and the client's family and must include services to be rendered, the frequency of visits or hours of service, identified problems, method of intervention, and

projected date of resolution. The care plan must be reviewed and updated by all appropriate staff members involved in client care at least annually, or more often as necessary to meet the needs of the client.

- (B) If a practitioner orders skilled treatment, then the appropriate health care professional must prepare a plan of care. The plan of care must be signed and approved by a practitioner in a timely manner. The plan of care must be developed in conjunction with agency staff and must cover all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits at the time of admission, prognoses, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, and any other appropriate items. The appropriate health care personnel must perform services as specified in the plan of care. The plan of care must be revised as necessary, but it must be reviewed and updated at least every six months.
- (c.) Agency staff must provide at least one home health service.
- (d.) All services must be provided and supervised by qualified personnel. The appropriate licensed health care professional must be available to supervise as needed, when services are provided. If medical social service is provided, the social worker must be licensed in the State of Texas to provide social work services.
- (e.) All staff providing services, delegation, and supervision must be employed by or be under contract with the agency.
- (f.) An agency is not required to employ home health aides. If an agency employs home health aides, the agency must comply with §558.701 of this chapter (relating to Home Health Aides).
- (g.) Unlicensed personnel employed by an agency to provide licensed home health services must:
 - (1.) have demonstrated competency in the task assigned when competency cannot be determined through education and experience; and
 - (2.) be at least 18 years of age or, if under 18 years of age, be a high school graduate or enrolled in a vocational education program.

§558.402 Standards Specific to Licensed and Certified Home Health Services

- (a.) In addition to the standards in Subchapter C of this chapter (relating to Minimum Standards for All Home and Community Support Services Agencies), an agency providing licensed and certified home health services must comply with applicable requirements of 42 United States Code Chapter 7, Subchapter XVII and the regulations in 42 CFR Part 484.
- (b.) An agency providing licensed and certified home health services that plans to implement a home health aide training and competency evaluation program must meet the requirements in §558.701(d)-(f) of this chapter (relating to Home Health Aides).

- (c.) An agency providing licensed and certified home health services that plans to implement a competency evaluation program must comply with §558.701(f) of this chapter.
- (d.) An agency providing licensed and certified home health services may not use an individual as a home health aide unless:
 - (1.) the individual has met the federal requirements under subsection (a) of this section;
 - (2.) the individual qualifies as a home health aide based on a:
 - (A) training and competency evaluation program, and the program meets the requirements of subsection (b) of this section; or
 - (B) competency evaluation program, and the program meets the requirements of subsection (c) of this section; or
 - (3.) the individual is a licensed health care provider.
- (e.) Since the individual's most recent completion of a training and competency evaluation program, or a competency evaluation program, if there has been a period of 24 consecutive months during which the individual has not furnished home health services, the individual will not be considered as having completed a training and competency evaluation program or a competency evaluation program.

§558.404 Standards Specific to Agencies Licensed to Provide Personal Assistance Services

- (a.) In addition to meeting the standards in Subchapter C of this chapter (relating to Minimum Standards for All Home and Community Support Services Agencies), an agency holding a license with the category of personal assistance services must meet the standards of this section.
- (b.) A person who is not licensed to provide personal assistance services under this chapter may not indicate or imply that the person is licensed to provide personal assistance services by using the words "personal assistance services" or in any other manner.
- (c.) Personal assistance services, as defined in §558.2 of this chapter (relating to Definitions), may be performed by an unlicensed person who is at least 18 years of age and has demonstrated competency, when competency cannot be determined through education and experience, to perform the tasks assigned by the supervisor. An unlicensed person who is under 18 years of age, is a high school graduate or is enrolled in a vocational educational program, and has demonstrated competency to perform the tasks assigned by the supervisor, may perform personal assistance services.
- (d.) The following tasks may be performed under a personal assistance services category:
 - (1.) personal care as defined in §558.2 of this chapter;
 - (2.) health-related tasks provided by unlicensed personnel that may be delegated by an RN, or that an RN determines do not require delegation, in accordance with the agency's written policy adopted, implemented, and enforced to ensure compliance with the rules adopted by the Texas Board of Nursing in 22 TAC Chapter 225 (relating to RN Delegation to Unlicensed Personnel and Tasks Not

Requiring Delegation in Independent Living Environments for Clients with Stable and Predictable Conditions);

- (3.) health-related tasks that are not the practice of professional nursing under the memorandum of understanding between HHSC and the Texas Board of Nursing; and
 - (4.) health-related tasks that are delegated by a physician under the Texas Occupations Code Chapter 157.
- (e.) The agency must ensure that when developing its operational policies, the policies are considerate of principles of individual and family choice and control, functional need, and accessible and flexible services.
- (f.) In addition to the client record requirements in §558.301(a)(9) of this chapter (relating to Client Records), the client file must include the following:
- (1.) documentation of determination of services based on an on-site visit by the supervisor where services will be primarily delivered and records of supervisory visits, if applicable;
 - (2.) individualized service plan developed, agreed upon, and signed by the client or family and the agency. The individualized service plan must include:
 - (A) types of services, supplies, and equipment to be provided;
 - (B) locations of services;
 - (C) frequency and duration of services;
 - (D) planned date of service initiation;
 - (E) charges for services rendered if the charges will be paid in full or in part by the client or significant other(s), or on request; and
 - (F) plan of supervision; and
 - (3.) documentation that the services have been provided according to the individualized service plan.
- (g.) In addition to the written policies required by §558.245 of this chapter (relating to Staffing Policies) the agency must adopt and enforce a written policy addressing the supervision of personnel with input from the client or family on the frequency of supervision.
- (1.) Supervision of personnel must be in accordance with the agency's policies and applicable State laws and rules, including rules adopted by the Texas Board of Nursing in 22 TAC Chapter 225.
 - (2.) A supervisor must be a licensed nurse or have completed two years of full-time study at an accredited college or university. An individual with a high school diploma or general equivalence diploma (GED) may substitute one year of full-time employment in a supervisory capacity in a health care facility, agency, or community-based agency for each required year of college.

- (3.) The client in a client managed attendant care program funded by HHSC or the Department of Assistive and Rehabilitative Services is not required to meet the standard in paragraph (2) of this subsection.
- (h.) Tube feedings and medication administration through a permanently placed gastrostomy tube (g-tube) in accordance with subsection (d)(3) of this section may be performed by an unlicensed person only after successful completion of the training and competency program and procedures described in paragraphs (1) - (5) of this subsection.
- (1.) The training and competency program for the performance of g-tube feedings by an unlicensed person must be taught by an RN, physician, physician assistant (PA), or qualified trainer. A qualified trainer must:
- (A) have successfully completed the training and competency program described in paragraphs (2) and (3) of this subsection taught by an RN, physician, or PA;
 - (B) have demonstrated upon return demonstration to an RN, physician, or PA the performance of the task and the ability to teach the task; and
 - (C) have been deemed competent by an RN, physician, or PA, to train unlicensed personnel in these procedures. Documentation of competency to perform, train, and teach must be maintained in the employee's or contractor's file. Competency must be evaluated and documented annually by an RN, physician, or PA.
- (2.) The minimum training program must include:
- (A) a description of the g-tube placement, including its purpose;
 - (B) infection control procedures and universal precautions to be used when performing g-tube feedings or medication administration through a g-tube;
 - (C) a description of conditions that must be reported to the client or the primary caregiver, or in the absence of the primary caregiver, to the agency administrator, supervisor, or the client's physician. The description of conditions must include a plan to be effected if the g-tube comes out or is not positioned correctly to ensure medical attention is provided within one hour;
 - (D) review of a written procedure for g-tube feeding or medication administration through a g-tube. The written procedure must be equivalent to current acceptable nursing standards of practice, including addressing the crushing of medications;
 - (E) conditions under which g-tube feeding or medication administration must not be performed; and
 - (F) demonstration of a g-tube feeding and medication administration to a client. If the trainee will become a qualified trainer, the demonstration must be done by the RN, PA, or physician. If the trainee will not become a qualified trainer, the demonstration may be done by an RN, PA, physician, or qualified trainer.

- (3.) The minimum competency evaluation must be documented and maintained in the employee's file and must include:
- (A) a score of 100 percent on a written multiple-choice test that consists of situational questions to include the criteria in paragraph (2)(A) - (E) of this subsection and an evaluation of the trainee's judgment and understanding of the essential skills, risks, and possible complications of a g-tube feeding or medication administration through a g-tube;
 - (B) a skills checklist demonstrating that the trainee has successfully completed the necessary skills for a g-tube feeding and medication administration via g-tube, and if the trainee will become a qualified trainer, the skills checklist must also demonstrate the ability to teach another person to perform the task. The skills checklist must be completed by an RN, physician, or PA, if the trainee will become a qualified trainer. The skills checklist for a trainee who will not become a qualified trainer may be completed by an RN, physician, PA, or qualified trainer; and
 - (C) documentation of an accurate demonstration of the g-tube feeding and medication administration performed by the trainee as required by paragraph (2)(F) of this subsection. If the trainee will become a qualified trainer, documentation of competency to teach this task must be maintained in the file of the qualified trainer. The person responsible for the training of the trainee must document the successful demonstration of the g-tube feeding and medication administration via g-tube by the trainee and the trainee's competency to perform this task in the trainee's file.
- (4.) The client or primary caregiver must provide information on the client's g-tube feeding or medication administration to the agency supervisor. If the client is not capable of directing his or her own care, the client's primary caregiver must be present to instruct and orient the supervisor regarding the client's g-tube feeding and medication regime. A copy of the current regime including unique conditions specific to the client must be placed in the client's file by the agency supervisor and provided to the respite caregiver. The respite caregiver must be oriented by the client, the client's primary caregiver, or the agency supervisor. The supervisor of the delivery of these services must have successfully completed a training and competency program outlined in paragraphs (2) and (3) of this subsection or be a qualified trainer.
- (5.) Legend medications that are to be administered must be in a legally labeled container from a pharmacy that contains the name of the client. Instructions for dosages according to weight or age for over-the-counter drugs commonly given the client must be furnished by the primary caregiver to the respite caregiver performing the tube feeding or medication administration.

§558.405 Standards Specific to Agencies Licensed to Provide Home Dialysis Services

- (a.) License designation. An agency may not provide peritoneal dialysis or hemodialysis services in a client's residence, independent living environment, or other appropriate location unless the agency holds a license to provide licensed home health or licensed and certified home health services and designated to provide home dialysis services. In order to receive a home dialysis designation, the agency must meet the licensing standards specified in this section and the standards for home health services in accordance with Subchapter C of this chapter (relating to Minimum Standards for All Home and Community Support Services Agencies) and §558.401 of this subchapter (relating to Standards Specific to Licensed Home Health Services), except for §558.401(b)(2)(A) and (B) of this subchapter. If there is a conflict between the standards specified in this section and those specified in Subchapter C of this chapter and §558.401 of this subchapter, the standards specified in this section will apply to the home dialysis services.
- (b.) Governing body. An agency must have a governing body. The governing body must appoint a medical director and the physicians who are on the agency's medical staff. The governing body must annually approve the medical staff policies and procedures. The governing body on a biannual basis must review and consider for approval continuing privileges of the agency's medical staff. The minutes from the governing body of the agency must be on file in the agency office.
- (c.) Qualifications and responsibilities of the medical director.
 - (1.) Qualifications. The medical director must be a physician licensed in the State of Texas who:
 - (A) is eligible for certification or is certified in nephrology or pediatric nephrology by a professional board; or
 - (B) during the five-year period prior to September 1, 1996, served at least 12 months as director of a dialysis facility or program.
 - (2.) Responsibilities. The medical director must:
 - (A) participate in the selection of a suitable treatment modality for all clients;
 - (B) assure adequate training of nurses in dialysis techniques;
 - (C) assure adequate monitoring of the client and the dialysis process; and
 - (D) assure the development and availability of a client care policy and procedures manual and its implementation.
- (d.) Personnel files. An agency must have individual personnel files on all physicians, including the medical director. The file must include the following:
 - (1.) a curriculum vitae which documents undergraduate, medical school, and all pertinent post graduate training; and
 - (2.) evidence of current licensure, and evidence of current United States Drug Enforcement Administration certification, Texas Department of Public Safety registration, and the board eligibility or certification, or the experience or training described in subsection (c)(1) of this section.

(e.) Provision of services. An agency that provides home staff-assisted dialysis must, at a minimum, provide nursing services, nutritional counseling, and medical social service. These services must be provided as necessary and as appropriate at the client's home, by telephone, or by a client's visit to a licensed ESRD facility in accordance with this subsection. The use of dialysis technicians in home dialysis is prohibited.

(1.)Nursing services.

(A) An RN, licensed by the State of Texas, who has at least 18 months experience in hemodialysis obtained within the last 24 months and has successfully completed the orientation and skills education described in subsection (f) of this section, must be available whenever dialysis treatments are in progress in a client's home. The agency administrator must designate a qualified alternate to this RN.

(B) Dialysis services must be supervised by an RN who meets the qualifications for a supervising nurse as set out in §558.244(c)(2) of this chapter (relating to Administrator Qualifications and Conditions and Supervising Nurse Qualifications).

(C) Dialysis services must be provided by a qualified licensed nurse who:

(i) is licensed as an RN or LVN by the State of Texas;

(ii) has at least 18 months experience in hemodialysis obtained within the last 24 months; and

(iii)has successfully completed the orientation and skills education described in subsection (f) of this section.

(2.)Nutritional counseling. A dietitian who meets the qualifications of this paragraph must be employed by or under contract with the agency to provide services. A qualified dietitian must meet the definition of dietitian in §558.2 of this chapter (relating to Definitions) and have at least one year of experience in clinical nutrition after obtaining eligibility for registration by the American Dietetic Association, Commission on Dietetic Registration.

(3.)Medical social services. A social worker who meets the qualifications established in this paragraph must be employed by or be under contract with the agency to provide services. A qualified social worker is a person who:

(A) is currently licensed under the laws of the State of Texas as a social worker and has a master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education; or

(B) has served for at least two years as a social worker, one year of which was in a dialysis facility or program prior to September 1, 1976, and has established a consultative relationship with a licensed master social worker.

(f.) Orientation, skills education, and evaluation.

(1.)All personnel providing dialysis in the home must receive orientation and skills education and demonstrate knowledge of the following:

- (A) anatomy and physiology of the normal kidney;
- (B) fluid, electrolyte, and acid-base balance;
- (C) pathophysiology of renal disease;
- (D) acceptable laboratory values for the client with renal disease;
- (E) theoretical aspects of dialysis;
- (F) vascular access and maintenance of blood flow;
- (G) technical aspects of dialysis;
- (H) peritoneal dialysis catheter, testing for peritoneal membrane equilibration, and peritoneal dialysis adequacy clearance, if applicable;
- (I) the monitoring of clients during treatment, beginning with treatment initiation through termination;
- (J) the recognition of dialysis complications, emergency conditions, and institution of the appropriate corrective action. This includes training agency personnel in emergency procedures and how to use emergency equipment;
- (K) psychological, social, financial, and physical complications of chronic dialysis;
- (L) care of the client with chronic renal failure;
- (M) dietary modifications and medications for the uremic client;
- (N) alternative forms of treatment for ESRD;
- (O) the role of renal health team members (physician, nurse, social worker, and dietitian);
- (P) performance of laboratory tests (hematocrit and blood glucose);
- (Q) the theory of blood products and blood administration; and
- (R) water treatment to include:
 - (i) standards for treatment of water used for dialysis as described in §3.2.1 (Hemodialysis Systems) and §3.2.2 (Maximum Level of Chemical Contaminants) of the American National Standard, Hemodialysis Systems, March 1992 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI), 3330 Washington Boulevard, Suite 500, Arlington, Virginia 22201. Copies of the standards are indexed and filed in the Texas Health and Human Services Commission, 701 W. 51st Street, Austin, Texas 78751, and are available for public inspection during regular working hours;
 - (ii) systems and devices;
 - (iii) monitoring; and
 - (iv) risks to clients of unsafe water.

- (2.) The requirements for the orientation and skills education period for licensed nurses are as follows.
- (A) The agency must develop an 80-hour written orientation program that includes classroom theory and direct observation of the licensed nurse performing procedures on a client in the home.
 - (i) The orientation program must be provided by an RN qualified under subsection (e)(1) of this section to supervise the provision of dialysis services by a licensed nurse
 - (ii) The licensed nurse must pass a written skills examination or competency evaluation at the conclusion of the orientation program and prior to the time the licensed nurse delivers independent client care.
 - (B) The licensed nurse must complete the required classroom component as described in paragraph (1)(A) - (E), (K) - (O), (Q) and (R) of this subsection and satisfactorily demonstrate the skills described in paragraph (1)(F) - (J) and (P) of this subsection. The orientation program may be waived by successful completion of the written examination as described in subparagraph (A)(ii) of this paragraph.
 - (C) The supervising nurse or qualified designee must complete an orientation competency skills checklist for each licensed nurse to reflect the progression of learned skills, as described in subsection (f)(1) of this section.
 - (D) Prior to the delivery of independent client care, the supervising nurse or qualified designee must directly supervise the licensed nurse for a minimum of three dialysis treatments and ensure satisfactory performance. Dependent upon the trainee's experience and accomplishments on the skills checklist, additional supervised dialysis treatments may be required.
 - (E) Continuing education for employees must be provided quarterly.
 - (F) Performance evaluations must be done annually.
 - (G) The supervising nurse or qualified designee must provide direct supervision to the licensed nurse providing dialysis services monthly, or more often if necessary. Direct supervision means that the supervising nurse is on the premises but not necessarily immediately present where dialysis services are being provided.
 - (g.) Hospital transfer procedure. An agency must establish an effective procedure for the immediate transfer to a local Medicare-certified hospital for clients requiring emergency medical care. The agency must have a written transfer agreement with such a hospital, or all physician members of the agency's medical staff must have admitting privileges at such a hospital.
 - (h.) Backup dialysis services. An agency that supplies home staff-assisted dialysis must have an agreement with a licensed ESRD facility to provide backup outpatient dialysis services.

- (i.) Coordination of medical and other information. An agency must provide for the exchange of medical and other information necessary or useful in the care and treatment of clients transferred between treating facilities. This provision must also include the transfer of the client care plan, hepatitis B status, and long-term program.
- (j.) Transplant recipient registry program. An agency must ensure that the names of clients awaiting cadaveric donor transplantation are entered in a recipient registry program.
- (k.) Testing for hepatitis B. An agency must conduct routine testing of home dialysis clients and agency employees to ensure detection of hepatitis B in employees and clients.
 - (1.) An agency must offer hepatitis B vaccination to previously unvaccinated, susceptible new staff members in accordance with 29 CFR §1910.1030(f)(1) - (2) (Bloodborne Pathogens).
 - (A) Staff vaccination records must be maintained in each staff member's personnel file.
 - (B) New staff members providing home dialysis care must be screened for hepatitis B surface antigen (HBsAg) and the results reviewed prior to the staff providing client care, unless the new staff member provides the agency documentation of positive serologic response to hepatitis B vaccine.
 - (C) An agency must establish, implement, and enforce a policy for repeated serologic screening of staff. The repeated serologic screening must be based on each staff member's HBsAg/antibody to HBsAg (anti-HBs) and must be congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Disease in the United States, 1993, published by the United States Department of Health and Human Services (USDHHS).
 - (2.) With the advice and consent of a client's nephrologist or attending physician, an agency must make the hepatitis B vaccine available to a client who is susceptible to hepatitis B, provided that the client has coverage or is willing to pay for vaccination.
 - (A) An agency must make available to clients literature describing the risks and benefits of the hepatitis B vaccination.
 - (B) Candidates for home dialysis must be screened for HBsAg within one month before or at the time of admission to the agency.
 - (C) Repeated serologic screening must be based on the antigen or antibody status of the client.
 - (D) Monthly screening for HBsAg is required for clients whose previous test results are negative for HBsAg.
 - (E) Screening of HbsAg-positive or anti-HbsAg-positive clients may be performed on a less frequent basis, provided that the agency's policy on this subject remains congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Diseases in the United States, 1993, published by the USDHHS.
- (l.) CPR certification. All direct client care employees must have current CPR certification.

- (m.) Initial admission assessment. Assessment of the client's residence must be made to ensure a safe physical environment for the performance of dialysis. The initial admission assessment must be performed by a qualified RN who meets the qualifications under subsection (e)(1)(A) of this section.
- (n.) Client long-term program. The agency must develop a long-term program for each client admitted to home dialysis. Criteria must be defined in writing and must provide guidance to the agency in the selection of clients suitable for home staff-assisted dialysis and in noting changes in a client's condition that would require discharge from the program. For the purposes of this subsection, Long-term program means the written documentation of the selection of a suitable treatment modality and dialysis setting, which has been selected by the client and the interdisciplinary team.
- (o.) Client history and physical. The agency must ensure that the history and physical is conducted upon the client's admission, or no more than six months prior to the date of admission, then annually after the date of admission.
- (p.) Physician orders. If home staff-assisted dialysis is selected, the physician must prepare orders outlining specifics of prescribed treatment.
 - (1.) If these physician's orders are received verbally, they must be confirmed in writing within a reasonable time frame. An agency must adopt and enforce a policy on the time frame for the countersignature of a physician's verbal orders. Medical orders for home staff-assisted dialysis must be revised as necessary but reviewed and updated at least every six months.
 - (2.) The initial orders for home staff-assisted dialysis must be received prior to the first treatment and must cover all pertinent diagnoses, including mental status, prognosis, functional limitations, activities permitted, nutritional requirements, medications and treatments, and any safety measures to protect against injury. Orders for home staff-assisted dialysis must include frequency and length of treatment, target weight, type of dialyzer, dialysate, dialysate flow rate, heparin dosage, and blood flow rate, and must specify the level of preparation required for the caregiver, such as an LVN or RN.
- (q.) Client care plan. The client care plan must be developed after consultation with the client and the client's family by the interdisciplinary team. The interdisciplinary team must include the physician, the RN, the dietitian, and the qualified social worker responsible for planning the care delivered to the home staff-assisted dialysis patient.
 - (1.) The initial client care plan must be completed by the interdisciplinary team within 10 calendar days after the first home dialysis treatment.
 - (2.) The client care plan must implement the medical orders and must include services to be rendered, such as the identification of problems, methods of intervention, and the assignment of health care personnel.
 - (3.) The client care plan must be in writing, be personalized for the individual, and reflect the ongoing medical, psychological, social, nutritional, and functional needs of the client, including treatment goals.

- (4.) The client care plan must include written evidence of coordination with other service providers, such as dialysis facilities or transportation providers, as needed to assure the provision of safe care.
- (5.) The client care plan must include written evidence of the client's or client's legal representative's input and participation, unless they refuse to participate. At a minimum, the client care plan must demonstrate that the content was shared with the client or the client's legal representative.
- (6.) For non-stabilized clients, where there is a change in modality, unacceptable laboratory work, uncontrolled weight changes, infections, or a change in family status, the client care plan must be reviewed at least monthly by the interdisciplinary team. Evidence of the review of the client care plan with the client and the interdisciplinary team to evaluate the client's progress or lack of progress toward the goals of the care plan, and interventions taken when progress toward stabilization or the goals are not achieved, must be documented and included in the client record.
- (7.) For a stable client, the client care plan must be reviewed and updated as indicated by any change in the client's medical, nutritional, or psychosocial condition or at least every six months. The long-term program must be revised as needed and reviewed annually. Evidence of the review of the client care plan with the client and the interdisciplinary team to evaluate the client's progress or lack of progress toward the goals of the care plan, and interventions taken when the goals are not achieved, must be documented and included in the client record.
- (r.) Medication administration. Medications must be administered only by licensed personnel.
- (s.) Client records. In addition to the applicable information described in §558.301(a)(9) of this chapter (relating to Client Records), records of home staff assisted dialysis clients must include the following:
 - (1.) a medical history and physical;
 - (2.) clinical progress notes by the physician, qualified licensed nurse, qualified dietitian, and qualified social worker;
 - (3.) dialysis treatment records;
 - (4.) laboratory reports;
 - (5.) a client care plan;
 - (6.) a long-term program; and
 - (7.) documentation of supervisory visits.
- (t.) Water treatment.
 - (1.) Water used for dialysis purposes must be analyzed for chemical contaminants every six months. Additional chemical analysis must be conducted if test results exceed the maximum levels of chemical contaminants listed in §3.2.2 (Maximum Level of Chemical Contaminants) of the American National Standards for

Hemodialysis Systems, March 1992 Edition, published by the AAMI. Copies of the standards are indexed and filed in the Texas Health and Human Services Commission, 701 W. 51st Street, Austin, Texas 78751, and are available for public inspection during regular working hours.

- (2.) Water used for dialysis must be treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques.
- (3.) Water used to prepare dialysate must meet the requirements set forth in §3.2.1 (Hemodialysis Systems) and §3.2.2 (Maximum Level of Chemical Contaminants), March 1992 Edition, published by the AAMI. Copies of the standards are indexed and filed in the Texas Health and Human Services Commission 701 W. 51st Street, Austin, Texas 78751, and are available for public inspection during regular working hours.
- (4.) Records of test results and equipment maintenance must be maintained at the agency.
- (u.) Equipment testing. An agency must adopt and enforce a policy to describe how the nurse will check the machine for conductivity, temperature, and pH prior to treatment, and describe the equipment required for these tests. The equipment must be available for use prior to each treatment. This policy must reflect current standards.
- (v.) Preventive maintenance for equipment. An agency must develop and enforce a written preventive maintenance program to ensure client care related equipment receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently if recommended by the manufacturer. The preventive maintenance may be provided by agency or contract staff qualified by training or experience in the maintenance of dialysis equipment.
- (1.) All equipment used by a client in home dialysis must be maintained free of defects, which could be a potential hazard to clients, the client's family, or agency personnel.
 - (A) Agency staff must be able to identify malfunctioning equipment and report such equipment to the appropriate agency staff. Malfunctioning equipment must be immediately removed from use.
 - (B) Written evidence of all preventive maintenance and equipment repairs must be maintained.
 - (C) After repairs or alterations are made to any equipment, the equipment must be thoroughly tested for proper operation before returning to service.
 - (D) An agency must comply with the federal Food, Drug, and Cosmetic Act, 21 United States Code (USC) §360i(b), concerning reporting when a medical device, as defined in 21 USC §321(h), has or may have caused or contributed to the injury or death of an agency client.

(E) In the event that the water used for dialysis purposes or home dialysis equipment is found not to meet safe operating parameters, and corrections cannot be effected to ensure safe care promptly, the client must be transferred to a licensed hospital (if inpatient care is required) or licensed ESRD facility until such time as the water or equipment is found to be operating within safe parameters.

(w.) Reuse or reprocessing of medical devices. Reuse or reprocessing of disposable medical devices, including but not limited to, dialyzers, end-caps, and blood lines must be in accordance with this subsection.

(1.) An agency's reuse practice must comply with the American National Standard, Reuse of Hemodialyzers, 1993 Edition, published by the AAMI. An agency must adopt and enforce a policy for dialyzer reuse criteria (including any agency-set number of reuses allowed) which is included in client education materials.

(2.) A transducer protector must be replaced when wetted during a dialysis treatment and must be used for one treatment only.

(3.) Arterial lines may be reused only when the arterial lines are labeled to allow for reuse by the manufacturer and the manufacturer-established protocols for the specific line have been approved by the United States Food and Drug Administration.

(4.) An agency must consider and address the health and safety of clients sensitive to disinfectant solution residuals.

(5.) An agency must provide each client and the client's family or legal representative with information regarding the reuse practices of the agency, the opportunity to tour the reuse facility used by the agency, and the opportunity to have questions answered.

(6.) An agency practicing reuse of dialyzers must:

(A) ensure that dialyzers are reprocessed via automated reprocessing equipment in a licensed ESRD facility or a centralized reprocessing facility;

(B) maintain responsibility and accountability for the entire reuse process;

(C) adopt and enforce policies to ensure that the transfer and transport of used and reprocessed dialyzers to and from the client's home does not increase contamination of the dialyzers, staff, or the environment; and

(D) ensure that HHSC staff has access to the reprocessing facility as part of an agency inspection.

(x.) Laboratory services. Provision of laboratory services must be as follows.

(1.) All laboratory services ordered for the client by a physician must be performed by a laboratory which meets the applicable requirements of 42 United States Code

(USC) §263a, concerning certification and certificates of waiver of a clinical laboratory (CLIA 1988) and in accordance with a written arrangement or agreement with the agency. CLIA 1988 applies to all agencies with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

- (2.) Copies of all laboratory reports must be maintained in the client's medical record.
 - (3.) Hematocrit and blood glucose tests may be performed at the client's home in accordance with §558.284 of this chapter (relating to Laboratory Services). Results of these tests must be recorded in the client's medical record and signed by the qualified licensed nurse providing the treatment. Maintenance, calibration, and quality control studies must be performed according to the equipment manufacturer's suggestions, and the results must be maintained at the agency.
 - (4.) Blood and blood products must only be administered to dialysis clients in their homes by a licensed nurse or physician.
- (y.) Home dialysis supplies. Supplies for home dialysis must meet the following requirements.
- (1.) All drugs, biologicals, and legend medical devices must be obtained for each client pursuant to a physician's prescription in accordance with applicable rules of the Texas State Board of Pharmacy.
 - (2.) In conjunction with the client's attending physician, the agency must ensure that there are sufficient supplies maintained in the client's home to perform the scheduled dialysis treatments and to provide a reasonable number of backup items for replacements, if needed, due to breakage, contamination, or defective products. All dialysis supplies, including medications, must be delivered directly to the client's home by a vendor of such products. However, agency personnel may transport prescription items from a vendor's place of business to the client's home for the client's convenience, so long as the item is properly labeled with the client's name and direction for use. Agency personnel may transport medical devices for reuse.
- (z.) Emergency procedures. The agency must adopt and enforce policies and procedures for medical emergencies and emergencies resulting from a disaster.
- (1.) Procedures must be individualized for each client to include the appropriate evacuation from the home and emergency telephone numbers. Emergency telephone numbers must be posted at each client's home and must include 911, if available, the number of the physician, the ambulance, the qualified RN on call for home dialysis, and any other phone number deemed as an emergency number.
 - (2.) The agency must ensure that the client and the client's family know the agency's procedures for medical emergencies and emergencies resulting from a disaster.
 - (3.) The agency must ensure that the client and the client's family know the procedure for disconnecting the dialysis equipment.
 - (4.) The agency must ensure that the client and the client's family know emergency call procedures.

- (5.) A working telephone must be available during the dialysis procedure.
- (6.) Depending on the kinds of medications administered, an agency must have available emergency drugs as specified by the medical director.
- (7.) In the event of a medical emergency or an emergency resulting from a disaster requiring transport to a hospital for care, the agency must assure the following:
 - (A) the receiving hospital is given advance notice of the client's arrival;
 - (B) the receiving hospital is given a description of the client's health status; and
 - (C) the selection of personnel, vehicle, and equipment are appropriate to effect a safe transfer.

§558.406 Standards for Agencies Providing Psychoactive Services

An agency that provides skilled nursing psychoactive treatments must comply with the requirements of this section.

- (1.) An agency must adopt and enforce a written policy relating to the provision of psychoactive treatments consistent with this section.
- (2.) Skilled nursing psychoactive treatments must be under the direction of a physician. Psychoactive treatments may only be provided by a physician or an RN.
- (3.) An RN providing skilled nursing psychoactive treatments must have one of the following qualifications:
 - (A) a master's degree in psychiatric or mental health nursing;
 - (B) a bachelor's degree in nursing with one year of full-time experience in an active treatment unit in a mental health facility or outpatient clinic;
 - (C) a diploma or associate degree with two years of full-time experience in an active treatment unit in a mental health facility or outpatient clinic; or
 - (D) for an RN for Medicare certified agencies, as allowed by the fiscal intermediary for Texas contracting with the United States Department of Health and Human Services (USDHHS) CMS.
- (4.) An agency must have written documentation that an RN providing skilled nursing psychoactive treatments is qualified under paragraph (3) of this section.
- (5.) The initial health assessment of a client receiving skilled nursing psychoactive treatments must include:
 - (A) mental status including psychological and behavioral status;
 - (B) sensory and motor function;
 - (C) cranial nerve function;
 - (D) language function; and
 - (E) any other criteria established by an agency's policy.

§558.407 Standards for Agencies Providing Home Intravenous Therapy

An agency furnishing intravenous therapy directly or under arrangement must comply with the following standards of care.

- (1.) A physician's order must be written specifically for intravenous therapy.
- (2.) Intravenous therapy must be provided by a licensed nurse.
- (3.) To ensure that prescribed care is administered safely, a licensed nurse must have the knowledge and documented competency to interpret and implement the written order.
- (4.) Written policies and procedures regarding the agency's provision of intravenous therapy must include, but are not limited to, addressing initiation, medication administration, monitoring, and discontinuation. Responsibilities of the licensed nurse must be clearly delineated in written policies and procedures.
- (5.) An RN must be available 24 hours a day.
- (6.) The client and caregiver must be assessed for the ability to safely administer the prescribed intravenous therapy, as per agency written criteria.
- (7.) If the client or caregiver is willing and able to safely administer the prescribed intravenous therapy, the agency must offer to teach the client or caregiver such administration. The teaching process is based on the client and caregiver needs and may include written instructions, verbal explanations, demonstrations, evaluation and documentation of competency, proficiency in performing intravenous therapy, scope of physical activities, and safe disposal of equipment.
- (8.) Actions must be implemented prior to and during all intravenous therapy to minimize the risk of anaphylaxis or other adverse reactions, as stated in the agency's written policy.
- (9.) An ongoing assessment of client and caregiver compliance in performing intravenous therapy related procedures must be done at periodic intervals.
- (10.) Care coordination must be provided to ensure continuity of care.
- (11.) The client and caregiver must be provided with 24-hour access to appropriate health care professionals employed by or having a contract with the agency.

Subchapter E, Licensure Surveys

Division 1 General

§558.501 Survey and Investigation Frequency

- (a.) At a minimum, HHSC conducts a survey:
 - (1.) after an agency submits a written request for an initial survey in accordance with §558.521 of this subchapter (relating to Requirements for an Initial Survey); and
 - (2.) within 18 months after conducting an initial survey and at least every 36 months thereafter.
- (b.) HHSC may conduct a survey or investigation to determine an agency's compliance with:

- (1.) this chapter or the Statute in the provision of licensed home health services, licensed and certified home health services, hospice services, or personal assistance services; and
 - (2.) federal requirements in the provision of licensed and certified home health services or licensed and certified hospice services.
- (c.) HHSC may conduct a survey for the renewal of a license or the issuance of a branch office or ADS license.

§558.503 Exemption from a Survey

Except for the investigation of complaints, an agency is exempt from additional surveys by HHSC if the agency maintains accreditation status for the services for which the agency seeks exemption and applicable to the agency's category of license from an accreditation organization with current HHSC approval. As of the effective date of this rule, accreditation organizations with current HHSC approval on its HCSSA licensure website are the Joint Commission, Community Health Accreditation Partner, and Accreditation Commission for Health Care, Inc.

§558.505 Notice of a Survey

HHSC does not announce or give prior notice of a survey to an agency.

§558.507 Agency Cooperation with a Survey

- (a.) By applying for or holding a license, an agency consents to entry and survey by a HHSC representative to verify compliance with the Statute or this chapter.
- (b.) An agency must provide the surveyor access to all agency records required by HHSC to be maintained by or on behalf of the agency.
- (c.) If a surveyor requests an agency record that is stored at a location other than the survey site, the agency must provide the record to the surveyor within eight working hours after the request.
- (d.) An agency must provide the surveyor with copies of agency records upon request.
- (e.) During a survey, agency staff must not:
 - (1.) make a false statement of a material fact about a matter under investigation by HHSC that a person knows, or should know, is false;
 - (2.) willfully interfere with the work of a HHSC representative;
 - (3.) willfully interfere with a HHSC representative in preserving evidence of a violation; or
 - (4.) refuse to allow a HHSC representative to inspect a book, record, or file required to be maintained by or on behalf of an agency.
- (f.) An agency must provide a HHSC representative with a reasonable and safe workspace, free from hazards, at which to conduct a survey at a parent office, branch office, or ADS.
- (g.) If there is a disagreement between the agency and a HHSC representative, the program manager or designee in the designated survey office determines what is reasonable and safe. After consulting with the program manager or designee and obtaining the program manager's agreement, the HHSC representative will notify the agency administrator or

designee if the requirement in subsection (f) of this section is not met. Within two working hours of this notice the agency must:

- (1.) provide a HHSC representative with a different workspace at the agency that meets the requirement in subsection (f) of this section; or
 - (2.) correct the unmet requirement in such a way as to allow the representative to reasonably and safely conduct the survey.
- (h.) If an agency willfully refuses to comply with subsection (g) of this section, thereby interfering with the work of the HHSC representative, the representative will terminate the survey and recommend enforcement action as described in subsection (i) of this section.
- (i.) HHSC may assess an administrative penalty without an opportunity to correct for a violation of provisions in this section, or may take other enforcement action to deny, revoke, or suspend a license, if an agency does not cooperate with a survey.

§558.509 Survey of a Branch Office, Alternate Delivery Site, and Services Provided

- (a.) If an agency is applying for or renewing a branch office or alternate delivery site license, a survey covers all locations.
- (b.) If an agency is applying for a license to provide more than one category of service, a survey covers all provided services of the agency.

Division 2 The Survey Process

§558.521 Requirements for an Initial Survey

- (a.) No later than six months after the effective date of an agency's initial license, an agency must:
- (1.) admit and provide services to clients as described in subsection (b) of this section; and
 - (2.) except as provided in subsection (f) of this section, submit a written request for an initial licensure survey to the designated survey office, as described in subsection (c) of this section.
- (b.) Before submitting a written request to HHSC for an initial licensure survey, an agency must admit clients and provide services as described in this subsection. The categories of service on an initial license may include licensed home health services (LHHS), LHHS with home dialysis designation, hospice services, and personal assistance services (PAS).
- (1.) When an initial license includes only one category of service, an agency must admit and provide services to at least one client.
 - (2.) When an initial license includes the LHHS and the PAS categories, an agency must admit and provide LHHS to at least one client.
 - (3.) When an initial license includes the LHHS and the LHHS with home dialysis designation categories, with or without the PAS category, an agency must admit and provide LHHS with home dialysis designation to at least one client.

- (4.) When an initial license includes the hospice services and the PAS categories, an agency must admit and provide hospice services to at least one client.
 - (5.) When an initial license includes the LHHS and the hospice services categories, with or without the PAS category, an agency must admit and provide LHHS services to at least one client and admit and provide hospice services to at least one client.
 - (6.) When an initial license includes the LHHS, the LHHS with home dialysis designation, and the hospice services categories, with or without the PAS category, an agency must admit and provide LHHS with home dialysis designation to at least one client. The agency must also admit and provide hospice services to at least one client.
- (c.) The agency's written request for an initial survey must be submitted to the designated survey office using HHSC Form 2020 Notification of Readiness for Initial Survey. The written request must include the name, date of admission, and the category of service provided to each client admitted for services to demonstrate that the agency has admitted clients and provided services as described in subsection (b) of this section.
- (d.) An agency must have the following information available and ready for review by a surveyor upon the surveyor's arrival at the agency:
- (1.) a list of clients who are receiving services or who have received services from the agency for each category of service licensed. The list must comply with the requirements of §558.293 of this chapter (relating to Client List and Services);
 - (2.) the client records for each client admitted during the licensing period before the initial survey;
 - (3.) all agency policies as required by this chapter; and
 - (4.) all personnel records of agency employees.
- (e.) HHSC may propose to deny an application to renew, or revoke or suspend, an initial license for the reasons specified in §558.15(c) of this chapter (relating to Issuance of an Initial License).
- (f.) An agency is not required to request an initial survey in accordance with subsection (a)(2) of this section if the agency is exempt from the survey as specified in §558.503 of this subchapter (relating to Exemption From a Survey). To demonstrate that it is exempt, the agency must send the accreditation documentation from the accreditation organization to the HHSC designated survey office no later than six months after the effective date of its license.
- (g.) If an agency receives written notice of accreditation from the accreditation organization after the agency submits a written request to HHSC for an initial licensure survey, the agency may demonstrate that it is exempt from the survey by sending the accreditation documentation to the HHSC designated survey office before HHSC arrives at the agency to conduct an initial survey.

§558.523 Personnel Requirements for a Survey

- (a.) For an initial survey, the administrator or alternate administrator must be present at the entrance conference, available in person or by telephone during the survey, and present in person at the exit conference.
- (b.) For a survey other than an initial survey, the administrator or alternate administrator must be available in person or by telephone during the entrance conference and the survey and must be present in person at the exit conference.
- (c.) The supervising nurse or alternate supervising nurse must be available in person or by telephone, if necessary, to provide information unique to the duties and functions of the position during the survey.
- (d.) If a required individual is unavailable during the survey process and is not at the agency when the surveyor arrives, the surveyor makes reasonable attempts to contact the individual.
- (e.) If a surveyor arrives during regular business hours and the agency is closed, an administrator, alternate administrator, or a designated agency representative must provide the surveyor entry to the agency within two hours after the surveyor's arrival at the agency. The administrator must designate in writing the agency representatives who may grant entry to a surveyor. The agency must comply with notice requirements described in §558.210 of this chapter (relating to Agency Operating Hours).
- (f.) If the surveyor is unable to contact a required individual or the agency fails to comply with subsection (e) of this section, the surveyor may recommend enforcement action against the agency.
- (g.) If compliance with this section would cause an interruption in client care being provided by the administrator, the alternate administrator, the supervising nurse, or the alternate supervising nurse, the administrator must contact its backup service provider to ensure continued client care.

§558.525 Survey Procedures

- (a.) Before beginning a survey, a surveyor holds an entrance conference, as specified in §558.523 of this division (relating to Personnel Requirements for a Survey), to explain the purpose of the survey and the survey process and provides an opportunity to ask questions.
- (b.) During a survey, a surveyor:
 - (1.) conducts at least three home visits to determine an agency's compliance with licensing requirements;
 - (2.) reviews any agency records that the surveyor believes are necessary to determine an agency's compliance with licensing requirements; and
 - (3.) evaluates an agency's compliance with each standard.
- (c.) An agency accredited by an accreditation organization must have the documentation of accreditation available at the time of a survey.

- (d.) HHSC keeps agency records confidential, except as allowed by Texas Health and Safety Code §142.009(d).
- (e.) A surveyor may remove original agency records from an agency only with the consent of the agency, as provided in Texas Health and Safety Code §142.009(e).

§558.527 Post-Survey Procedures

- (a.) After a survey is completed, the surveyor holds an exit conference with the administrator or alternate administrator to inform the agency of the preliminary findings.
- (b.) An agency may make an audio recording of the exit conference only if the agency:
 - (1.) records two tapes simultaneously;
 - (2.) allows the surveyor to review the tapes; and
 - (3.) gives the surveyor the tape of the surveyor's choice before leaving the agency.
- (c.) An agency may make a video recording of the exit conference only if the surveyor agrees to allow it and if the agency:
 - (1.) records two tapes simultaneously;
 - (2.) allows the surveyor to review the tapes; and
 - (3.) gives the surveyor the tape of the surveyor's choice before leaving the agency.
- (d.) An agency may submit additional written documentation and facts after the exit conference only if the agency describes the additional documentation and facts to the surveyor during the exit conference.
 - (1.) The agency must submit the additional written documentation and facts to the designated survey office within two working days after the end of the exit conference.
 - (2.) If an agency properly submits additional written documentation, the surveyor may add the documentation to the record of the survey.
- (e.) If HHSC identifies additional violations or deficiencies after the exit conference, HHSC holds an additional face-to-face exit conference with the agency regarding the additional violations or deficiencies.
- (f.) HHSC provides official written notification of the survey findings to the agency within 10 working days after the exit conference.
- (g.) The official written notification of the survey findings includes a statement of violations, condition-level deficiencies, or both, cited by HHSC against the agency as a result of the survey, and instructions for submitting an acceptable plan of correction, and for requesting IDR.
 - (1.) If the official written notification of the survey findings declares that an agency is in violation of the Statute or this chapter, an agency must follow HHSC instructions included with the statement of violations for submitting an acceptable plan of correction.

- (2.) An acceptable plan of correction includes the corrective measures and time frame with which the agency must comply to ensure correction of a violation. If an agency fails to correct each violation by the date on the plan of correction, HHSC may take enforcement action against the agency. An agency must correct a violation in accordance with the following time frames:
- (A) A Severity Level B violation that results in serious harm to or death of a client or constitutes a serious threat to the health or safety of a client, must be addressed upon receipt of the official written notice of the violations and corrected within two days.
 - (B) A Severity Level B violation that substantially limits the agency's capacity to provide care must be corrected within seven days after receipt of the official written notice of the violations.
 - (C) A Severity Level A violation that has or had minor or no health or safety significance must be corrected within 20 days after receipt of the official written notice of the violations.
 - (D) A violation that is not designated as Severity Level A or Severity Level B must be corrected within 60 days after the date the violation was cited.
- (3.) An agency must submit an acceptable plan of correction for each violation or deficiency no later than 10 days after its receipt of the official written notification of the survey findings.
- (4.) If HHSC finds the plan of correction unacceptable, HHSC gives the agency written notice and provides the agency one additional opportunity to submit an acceptable plan of correction. An agency must submit a revised plan of correction no later than 30 days after the agency's receipt of HHSC written notice of an unacceptable plan of correction.
- (h.) An acceptable plan of correction does not preclude HHSC from taking enforcement action against an agency.
- (i.) An agency must submit a plan of correction in response to an official written notification of survey findings that declares a violation or deficiency even if the agency disagrees with the survey findings.
- (j.) If an agency disagrees with the survey findings citing a violation or condition-level deficiency, the agency may request IDR to refute the violation or deficiency.
- (1.) HHSC does not grant an agency's request for IDR if:
 - (A) HHSC cited the violation or deficiency at the agency's immediately preceding survey; and
 - (B) HHSC cited the violation or deficiency again, with no new findings.
 - (2.) To request IDR, an agency must:
 - (A) mail or fax a complete and accurate IDR request form to the address or fax number listed on the form, which must be postmarked or faxed within 10 days after the date of receipt of the official written notification of the survey findings;

- (B) mail or fax a rebuttal letter and supporting documentation to the address or fax number listed on the IDR request form and ensure receipt by the HHSC Survey and Certification Enforcement Unit within seven days after the postmark or fax date of the IDR request form; and
 - (C) mail or fax a copy of the IDR request form, rebuttal letter, and supporting documentation to the designated survey office within the same time frames each is submitted to the HHSC Survey and Certification Enforcement Unit.
- (3.) An agency may not submit information after the deadlines established in paragraph (2)(A) and (B) of this subsection unless HHSC requests additional information. The agency's response to HHSC request for information must be received within three working days after the request is made.
 - (4.) An agency waives its right to IDR if the agency fails to submit the required information to the HHSC Survey and Certification Enforcement Unit within the required time frames.
 - (5.) An agency must present sufficient information to the HHSC Survey and Certification Enforcement Unit to support the agency's desired IDR outcome.
 - (6.) The rebuttal letter and supporting documentation must include:
 - (A) identification of the disputed deficiencies or violations;
 - (B) the reason the deficiencies or violations are disputed;
 - (C) the desired outcome for each disputed deficiency or violation; and
 - (D) copies of client records, policies and procedures, and other documentation and information that directly demonstrate that the condition-level deficiency or violation should not have been cited.
 - (7.) The written decision issued by HHSC after the completion of its review is the final decision from IDR.

Subchapter F Enforcement

§558.601 Enforcement Actions

- (a.) Enforcement actions. HHSC may take the following enforcement actions against an agency:
 - (1.) license suspension;
 - (2.) immediate license suspension;
 - (3.) license revocation;
 - (4.) immediate license revocation;
 - (5.) administrative penalties; and
 - (6.) denial of license application.
- (b.) Denial of license application. HHSC may deny a license application for the reasons set out in §558.21 of this chapter (relating to Denial of an Application or a License).

(c.) Suspension or revocation.

- (1.) HHSC may suspend or revoke an agency's license if the license holder, the controlling person, the affiliate, the administrator, or the alternate administrator:
 - (A) fails to comply with this chapter;
 - (B) fails to comply with the Statute; or
 - (C) violates Texas Occupations Code §102.001 (relating to Soliciting Patients; Offense) and §102.006 (relating to Failure to Disclose; Offense).
- (2.) HHSC may suspend or revoke an agency's license to provide licensed and certified home health services if the agency fails to maintain its certification qualifying the agency as a certified agency, as referenced in Texas Health and Safety Code §142.011(c).

(d.) Administrative penalties.

- (1.) HHSC may assess an administrative penalty against an agency in accordance with §558.602 of this subchapter (relating to Administrative Penalties).
- (2.) HHSC may consider the assessment of past administrative penalties when considering another enforcement action against an agency.

(e.) Immediate licensure suspension or revocation. HHSC may immediately suspend or revoke an agency's license when the health and safety of persons are threatened.

- (1.) If HHSC issues an order for immediate suspension or revocation of the agency's license, HHSC provides immediate notice to the controlling person, administrator, or alternate administrator of the agency by fax and either by certified mail with return receipt requested or hand-delivery. The notice includes:
 - (A) the action taken;
 - (B) legal grounds for the action;
 - (C) the procedure governing appeal of the action; and
 - (D) the effective date of the order.
- (2.) An order for immediate suspension or revocation goes into effect immediately.
- (3.) An agency is entitled to a formal administrative hearing not later than seven days after the effective date of the order for immediate suspension or revocation.
- (4.) If an agency requests a formal administrative hearing, the hearing is held in accordance with the Texas Government Code Chapter 2001, and with the formal hearing procedures in 1 TAC Chapter 357, Subchapter I (relating to Hearings Under the Administrative Procedure Act) and 40 TAC Chapter 91 (relating to Hearings Under the Administrative Procedure Act).

(f.) Opportunity to show compliance.

- (1.) Before revocation or suspension of an agency's license or denial of an application for the renewal of an agency's license, HHSC gives the license holder:

- (A) a notice by personal service or by registered or certified mail of the facts or conduct alleged to warrant the proposed action, with a copy sent to the agency; and
- (B) an opportunity to show compliance with all requirements of law for the retention of the license by sending HHSC Regulatory Services office a written request. The request must:
 - (i) be postmarked within 10 days after the date of HHSC notice and be received in HHSC Regulatory Services office within 10 days after the date of the postmark; and
 - (ii) contain specific documentation refuting HHSC allegations.
- (2.) HHSC limits its review to the documentation submitted by the license holder and information HHSC used as the basis for its proposed action. An agency may not attend HHSC meeting to review the opportunity to show compliance. HHSC gives a license holder a written affirmation or reversal of the proposed action.
- (3.) After an opportunity to show compliance, HHSC sends a license holder a written notice that:
 - (A) informs the license holder of HHSC decision; and
 - (B) provides the agency with an opportunity to appeal HHSC decision through a formal hearing process.
- (g.) Notice of denial of application for license or renewal of a license, suspension or revocation of license. HHSC sends an applicant or license holder notice by fax and either by certified mail with return receipt requested or hand-delivery of HHSC denial of an application for an initial license or renewal of a license, suspension of a license or revocation of a license.
- (h.) Formal appeal. An applicant or license holder has the right to make a formal appeal after receipt of HHSC notification of denial of an application for an initial license or renewal of a license and suspension or revocation of a license.
 - (1.) An agency must request a formal administrative hearing within 20 days of receipt of HHSC notice of denial of an application for an initial license or renewal of a license, suspension of a license, or revocation of a license. To make a formal appeal, the applicant or agency must comply with the formal hearing procedures in 1 TAC Chapter 357, Subchapter I and 40 TAC Chapter 91.
 - (2.) HHSC presumes receipt of HHSC notice to occur on the 10th day after the notice is mailed to the last known address, unless another date is reflected on the return receipt.
 - (3.) If an agency does not meet the deadline for requesting a formal hearing, the agency has lost its opportunity for a formal hearing, and HHSC takes the proposed action.
 - (4.) A formal administrative hearing is held in accordance with Government Code, Chapter 2001, and the formal hearing procedures in 1 TAC Chapter 357, Subchapter I and 40 TAC Chapter 91.

- (5.) Except for the denial of an application for an initial license, if an agency appeals, the license remains valid until all appeals are final, unless the license expires without a timely application for renewal submitted to HHSC. The agency must continue to submit a renewal application in accordance with §558.17 of this chapter (relating to Application Procedures for a Renewal License) until the action to revoke, suspend, or deny renewal of the license is completed. However, HHSC does not renew the license until it determines the reason for the proposed action no longer exists.
- (6.) If an agency appeals, the enforcement action will take effect when all appeals are final, and the proposed enforcement action is upheld. If the agency wins the appeal, the proposed action does not happen.
- (7.) If HHSC suspends a license, the suspension remains in effect until HHSC determines that the reason for suspension no longer exists. A suspension may last no longer than the term of the license. HHSC conducts a survey of the agency before making a determination to recommend cancellation of a suspension.
- (8.) If HHSC revokes or does not renew a license and one year has passed following the effective date of revocation or denial of licensure renewal, a person may reapply for a license by complying with the requirements and procedures in §558.13 of this chapter (relating to Obtaining an Initial License). HHSC does not issue a license if the reason for revocation or nonrenewal continues to exist.
- (i.) Agency dissolution. Upon suspension, revocation, or nonrenewal of a license, the license holder must:
 - (1.) return the original license to HHSC; and
 - (2.) implement its written plan required in §558.291 of this chapter (relating to Agency Dissolution).

§558.602 Administrative Penalties

- (a.) Assessing penalties. HHSC may assess an administrative penalty against a person who violates:
 - (1.) the Statute;
 - (2.) a provision in this chapter for which a penalty may be assessed; or
 - (3.) Texas Occupations Code §102.001 (relating to Soliciting Patients; Offense) or §102.006 (relating to Failure to Disclose; Offense), if related to the provision of home health, hospice, or personal assistance services.
- (b.) Criteria for assessing penalties. HHSC assesses administrative penalties in accordance with the schedule of appropriate and graduated penalties established in this section.
 - (1.) The schedule of appropriate and graduated penalties for each violation is based on the following criteria:
 - (A) the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation and the hazard of the violation to the health or safety of clients;

- (B) the history of previous violations by a person or a controlling person with respect to that person;
- (C) whether the affected agency identified the violation as part of its internal quality assurance process and made a good faith, substantial effort to correct the violation in a timely manner;
- (D) the amount necessary to deter future violations;
- (E) efforts made to correct the violation; and
- (F) any other matters that justice may require.

(2.) In determining which violation warrants a penalty, HHSC considers:

- (A) the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation and the hazard of the violation to the health or safety of clients; and
- (B) whether the affected agency identified the violation as part of its internal quality assurance program and made a good faith, substantial effort to correct the violation in a timely manner.

(c.) Opportunity to correct. Except as provided in subsections (e) and (f) of this section, HHSC provides an agency with an opportunity to correct a violation in accordance with the time frames established in §558.527(g)(2) of this chapter (relating to Post-Survey Procedures) before assessing an administrative penalty if a plan of correction has been implemented.

(d.) Minor violations.

- (1.) HHSC may not assess an administrative penalty for a minor violation unless the violation is of a continuing nature or is not corrected in accordance with an accepted plan of correction.
- (2.) HHSC may assess an administrative penalty for a subsequent occurrence of a minor violation when cited within three years from the date the agency first received written notice of the violation.
- (3.) HHSC does not assess an administrative penalty for a subsequent occurrence of a minor violation when cited more than three years from the date the agency first received written notice of the violation.

(e.) No opportunity to correct. HHSC may assess an administrative penalty without providing an agency with an opportunity to correct a violation if HHSC determines that the violation:

- (1.) results in serious harm to or death of a client;
- (2.) constitutes a serious threat to the health or safety of a client;
- (3.) substantially limits the agency's capacity to provide care;
- (4.) involves the provisions of Texas Human Resources Code Chapter 102, Rights of the Elderly;
- (5.) is a violation in which a person:

- (A) makes a false statement, that the person knows or should know is false of a material fact:
 - (i) on an application for issuance or renewal of a license or in an attachment to the application; or
 - (ii) with respect to a matter under investigation by HHSC;
 - (B) refuses to allow a representative of HHSC to inspect a book, record, or file required to be maintained by an agency;
 - (C) willfully interferes with the work of a representative of HHSC or the enforcement of this chapter;
 - (D) willfully interferes with a representative of HHSC preserving evidence of a violation of this chapter or a rule, standard, or order adopted, or license issued under this chapter;
 - (E) fails to pay a penalty assessed by HHSC under this chapter within 10 days after the date the assessment of the penalty becomes final; or
 - (F) fails to submit:
 - (i) a plan of correction within 10 days after the date the person receives a statement of licensing violations; or
 - (ii) an acceptable plan of correction within 30 days after the date the person receives notification from HHSC that the previously submitted plan of correction is not acceptable.
- (f.) Violations relating to Advance Directives. As provided in Texas Health and Safety Code §142.0145, HHSC assesses an administrative penalty of \$500 for a violation of §558.283 of this chapter (relating to Advance Directives) without providing an agency with an opportunity to correct the violation.
- (g.) Penalty calculation and assessment.
- (1.) Each day that a violation occurs before the date on which the person receives written notice of the violation is considered one violation.
 - (2.) Each day that a violation occurs after the date on which an agency receives written notice of the violation constitutes a separate violation.
- (h.) Schedule of appropriate and graduated penalties.
- (1.) If two or more rules listed in paragraphs (2) and (3) of this subsection relate to the same or similar matter, one administrative penalty may be assessed at the higher severity level violation.
 - (2.) Severity Level A violations.
 - (A) The penalty range for a Severity Level A violation is \$100 - \$250 per violation.
 - (B) A Severity Level A violation is a violation that has or has had minor or no client health or safety significance.

- (C) HHSC assesses a penalty for a Severity Level A violation only if the violation is of a continuing nature or was not corrected in accordance with an accepted plan of correction.
- (D) HHSC may assess a separate Severity Level A administrative penalty for each of the rules listed in the following table.

[Attached Graphic](#)

(3.)Severity Level B violations.

- (A) The penalty range for a Severity Level B violation is \$500-\$1,000 per violation.
- (B) A Severity Level B violation is a violation that:
 - (i) results in serious harm to or death of a client;
 - (ii) constitutes an actual serious threat to the health or safety of a client; or
 - (iii)substantially limits the agency's capacity to provide care.
- (C) The penalty for a Severity Level B violation that:
 - (i) results in serious harm to or death of a client is \$1,000;
 - (ii) constitutes an actual serious threat to the health or safety of a client is \$500 - \$1,000; and
 - (iii)substantially limits the agency's capacity to provide care is \$500 - \$750
- (D) As provided in subsection (e) of this section, a Severity Level B violation is a violation for which HHSC may assess an administrative penalty without providing an agency with an opportunity to correct the violation.
- (E) HHSC may assess a separate Severity Level B administrative penalty for each of the rules listed in the following table.

[Attached Graphic](#)

- (i.) Violations for which HHSC may assess an administrative penalty of \$500.
 - (1.)HHSC may assess an administrative penalty of \$500 for each of the violations listed in subsection (e)(4) and (5) of this section, without providing an agency with an opportunity to correct the violation.
 - (2.)A separate penalty may be assessed for each of these violations.
- (j.) Proposal of administrative penalties.
 - (1.)If HHSC assesses an administrative penalty, HHSC provides a written notice of violation letter to an agency. The notice includes:
 - (A) a summary of the violation;
 - (B) the amount of the proposed penalty; and
 - (C) a statement of the agency's right to a formal administrative hearing on the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty.
 - (2.)An agency may accept HHSC determination within 20 days after the date on which the agency receives the notice of violation letter, including the proposed penalty, or may make a written request for a formal administrative hearing on the determination.

- (A) If an agency notified of a violation accepts HHSC determination, the HHSC executive commissioner or the HHSC executive commissioner's designee issues an order approving the determination and ordering that the agency pay the proposed penalty.
- (B) If an agency notified of a violation does not accept HHSC determination, the agency must submit to the Health and Human Services Commission a written request for a formal administrative hearing on the determination and must not pay the proposed penalty. Remittance of the penalty to HHSC is deemed acceptance by the agency of HHSC determination, is final, and waives the agency's right to a formal administrative hearing.
- (C) If an agency notified of a violation fails to respond to the notice of violation letter within the required time frame, the HHSC executive commissioner or the HHSC executive commissioner's designee issues an order approving the determination and ordering that the agency pay the proposed penalty.
- (D) If an agency requests a formal administrative hearing, the hearing is held in accordance with the Statute §142.0172, §142.0173, and the formal hearing procedures in 1 TAC Chapter 357, Subchapter I (relating to Hearings Under the Administrative Procedure Act), and 40 TAC Chapter 91 (relating to Hearings Under the Administrative Procedure Act).

§558.603 Court Action

- (a.) If a person operates an agency without a license issued under this chapter, the person is liable for a civil penalty of not less than \$1,000 or more than \$2,500 for each day of violation.
- (b.) If a person violates the licensing requirements of the Statute, HHSC may petition the district court to restrain the person from continuing the violation.

§558.604 Surrender or Expiration of a License

- (a.) After a survey in which a surveyor cited deficiencies, an agency may surrender its license or allow its license to expire to avoid enforcement action by HHSC.
- (b.) If an agency surrenders its license before the expiration date, the agency must return its original license and provide the following information to HHSC:
 - (1.) the effective date of closure;
 - (2.) the location of client records;
 - (3.) the name and address of the client record custodian;
 - (4.) a statement signed and dated by the license holder agreeing to the surrender of the license; and
 - (5.) the disposition of active clients at the time of closure.

- (c.) If an agency surrenders its license or allows its license to expire, HHSC denies an application for license by the agency, its license holder, and its affiliate for one year after the date of the surrender or expiration.

Subchapter G Home Health Aides

§558.701 Home Health Aides

- (a.) A home health aide may be used by an agency providing licensed home health services if the aide meets one of the following requirements:
- (1.) a minimum of one year of full-time experience in direct client care in an institutional setting (hospital or nursing facility);
 - (2.) one year of full-time experience within the last five years in direct client care in an agency setting;
 - (3.) satisfactorily completed a training and competency evaluation program that complies with the requirements of this section;
 - (4.) satisfactorily completed a competency evaluation program that complies with the requirements of this section;
 - (5.) submitted to the agency documentation from the director of programs or the dean of a school of nursing that states that the individual is a nursing student who has demonstrated competency in providing basic nursing skills in accordance with the school's curriculum; or
 - (6.) listed on the HHSC nurse aide registry (NAR) with no finding against the aide relating to client abuse or neglect or misappropriation of client property.
- (b.) A home health aide must have provided home health services within the previous 24 months to qualify under subsection (a)(3) or (4) of this section.
- (c.) Assignment, delegation, and supervision of services provided by home health aides must be performed in accordance with rules in this chapter governing the agency's license category.
- (d.) The training portion of a training and competency evaluation program for home health aides must be conducted by or under the general supervision of an RN who possesses a minimum of two years of nursing experience, at least one year of which must be in the provision of home health care. The training program may contain other aspects of learning, but must contain the following:
- (1.) a minimum of 75 hours as follows:
 - (A) an appropriate number of hours of classroom instruction; and
 - (B) a minimum of 16 hours of clinical experience, which will include in-home training and must be conducted in a home, hospital, nursing home, or laboratory;
 - (2.) completion of at least 16 hours of classroom training before a home health aide begins clinical experience working directly with clients under the supervision of qualified instructors;

- (3.) if LVN instructors are used for the training portion of the program, the following qualifications and supervisory requirements apply:
 - (A) an LVN may provide the home health aide classroom training under the supervision of an RN who has two years of nursing experience, at least one year of which must be in the provision of home health care;
 - (B) LVNs, as well as RNs, may supervise home health aide candidates in the course of the clinical experience; and
 - (C) an RN must maintain overall responsibility for the training and supervision of all home health aide training students; and
 - (4.) an assessment that the student knows how to read and write English and carry out directions.
- (e.) The classroom instruction and clinical experience content of the training portion of a training and competency evaluation program must include, but is not limited to:
- (1.) communication skills;
 - (2.) observation, reporting, and documentation of a client's status and the care or service furnished;
 - (3.) reading and recording temperature, pulse, and respiration;
 - (4.) basic infection control procedures and instruction on universal precautions;
 - (5.) basic elements of body functioning and changes in body function that must be reported to an aide's supervisor;
 - (6.) maintenance of a clean, safe, and healthy environment;
 - (7.) recognizing emergencies and knowledge of emergency procedures;
 - (8.) the physical, emotional, and developmental needs of and ways to work with the populations served by the agency including the need for respect for the client and his or her privacy and property;
 - (9.) appropriate and safe techniques in personal hygiene and grooming that include:
 - (A) bed bath;
 - (B) sponge, tub, or shower bath;
 - (C) shampoo, sink, tub, or bed;
 - (D) nail and skin care;
 - (E) oral hygiene; and
 - (F) toileting and elimination;
 - (10.) safe transfer techniques and ambulation;
 - (11.) normal range of motion and positioning;
 - (12.) adequate nutrition and fluid intake;

- (13.) any other task the agency may choose to have the home health aide perform in accordance with §558.298 of this chapter (relating to Delegation of Nursing Tasks by Registered Professional Nurses to Unlicensed Personnel and Tasks Not Requiring Delegation); and
 - (14.) the rights of the elderly.
- (f.) This section addresses the requirements for the competency evaluation program or the competency evaluation portion of a training and competency evaluation program.
- (1.) The competency evaluation must be performed by an RN.
 - (2.) The competency evaluation must address each of the subjects listed in subsection (e)(2) - (13) of this section.
 - (3.) Each of the areas described in subsection (e)(3) and (9) - (11) of this section must be evaluated by observation of the home health aide's performance of the task with a client or person.
 - (4.) Each of the areas described in subsection (e)(2), (4) - (8), (12), and (13) of this section may be evaluated through written examination, oral examination, or by observation of a home health aide with a client.
 - (5.) A home health aide is not considered to have successfully completed a competency evaluation if the aide has an unsatisfactory rating in more than one of the areas described in subsection (e)(2) - (13) of this section.
 - (6.) If an aide receives an unsatisfactory rating, the aide must not perform that task without direct supervision by an RN or LVN, until the aide receives training in the task for which he or she was evaluated as unsatisfactory and successfully completes a subsequent competency evaluation with a satisfactory rating on the task.
 - (7.) If an individual fails to complete the competency evaluation satisfactorily, the individual must be advised of the areas in which he or she is inadequate.
- (g.) If a person, who is not an agency licensed under this section, desires to implement a home health aide training and competency evaluation program or a competency evaluation program, the person must meet the requirements of this section in the same manner as set forth for an agency.

Subchapter H Standards Specific to Agencies Licensed to Provide Hospice Services

Division 1 Hospice General Provisions

§558.801 Subchapter H Applicability

- (a.) This subchapter applies to an agency licensed with the hospice services category. An agency licensed to provide hospice services must adopt and enforce written policies in accordance with this subchapter.
- (b.) A hospice that provides inpatient care directly in its own inpatient unit must comply with the additional standards in Division 7 of this subchapter (relating to Hospice Inpatient Units).

- (c.) A hospice that provides hospice care to a resident of a skilled nursing facility, nursing facility, or an intermediate care facility for individuals with an intellectual disability or related conditions, must comply with the additional standards in Division 8 of this subchapter (relating to Hospices that Provide Hospice Care to Residents of a Skilled Nursing Facility, Nursing Facility, or Intermediate Care Facility for Individuals with an Intellectual Disability or Related Conditions).
- (d.) A Medicare-certified hospice agency must comply with the Medicare Conditions of Participation in 42 CFR Part 418, Hospice Care.
- (e.) A person who is not licensed to provide hospice services may not use the word "hospice" in a title or description of a facility, organization, program, service provider, or services or use any other words, letters, abbreviations, or insignia indicating or implying that the person holds a license to provide hospice services.
- (f.) For the purposes of this subchapter, the term "attending practitioner:"
 - (1.) includes a physician or an advanced practice nurse identified by a hospice client at the time he or she elects to receive hospice services as having the most significant role in the determination and delivery of the client's medical care; and
 - (2.) is synonymous with "attending physician," as defined in 42 CFR §418.3.
- (g.) For the purposes of this subchapter, election of hospice care occurs on the effective date included in a client's hospice election statement. A hospice election statement must include:
 - (1.) identification of the hospice that will provide care to the client;
 - (2.) the client's or the client's legal representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the client's terminal illness, as well as the potential availability of supportive palliative care options outside a hospice setting;
 - (3.) acknowledgement by Medicare beneficiaries that certain Medicare services, as described in 42 CFR §418.24(d), are waived by the hospice election;
 - (4.) the effective date of the election of hospice care, which may be later but not earlier than the date of the client's or the client's legal representative's signature and may be the first day of hospice care or a later date; and
 - (5.) the signature of the client or legal representative.
- (h.) For the purposes of this subchapter, the term "comprehensive assessment" means a thorough evaluation of a client's physical, psychosocial, emotional, and spiritual status related to the terminal illness and related conditions. This includes a thorough evaluation of the caregiver's and family's willingness and capability to care for the client.

Division 2 Initial and Comprehensive Assessment of a Hospice

§558.810 Hospice Initial Assessment

- (a.) A hospice RN must complete an initial assessment of a client where hospice services will be delivered within 48 hours after the election of hospice care, unless the client's

physician, the client, or the client's legal representative requests that the initial assessment be completed in less than 48 hours.

- (b.) The initial assessment must assess a client's immediate physical, psychosocial, and emotional status related to the terminal illness and related conditions. The information gathered must be used by the hospice to begin the plan of care and to provide care and services to treat a client's and a client's family's immediate care and support needs.

§558.811 Hospice Comprehensive Assessment

- (a.) The hospice must conduct and document a client-specific comprehensive assessment that identifies a client's need for hospice care and services. The comprehensive assessment must:
 - (1.) identify the client's physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the client's well-being, comfort, and dignity throughout the dying process;
 - (2.) include all areas of hospice care related to the palliation and management of the client's terminal illness and related conditions;
 - (3.) accurately reflect the client's health status at the time of the comprehensive assessment and include information to establish and monitor a plan of care; and
 - (4.) identify the caregiver's and family's willingness and capability to care for the client.
- (b.) The hospice interdisciplinary team, in consultation with the client's attending practitioner, if any, must complete the comprehensive assessment within five days after the election of hospice care.
- (c.) The comprehensive assessment must take into consideration the following factors:
 - (1.) the nature of the condition causing admission, including the presence or lack of objective data and the client's subjective complaints;
 - (2.) complications and risk factors that could affect care planning;
 - (3.) the client's functional status, including the client's ability to understand and participate in the client's own care;
 - (4.) the imminence of the client's death;
 - (5.) the severity of the client's symptoms;
 - (6.) a review of all the client's prescription and over-the-counter drugs, herbal remedies, and other alternative treatments that could affect drug therapy, to identify the following:
 - (A) the effectiveness of drug therapy;
 - (B) drug side effects;
 - (C) actual or potential drug interactions;
 - (D) duplicate drug therapy; and
 - (E) drug therapy currently associated with laboratory monitoring;

- (7.)an initial bereavement assessment of the needs of the client's family and other persons that:
 - (A) focuses on the social, spiritual, and cultural factors that may impact their ability to cope with the client's death; and
 - (B) gathers information that must be incorporated into the plan of care and considered in the bereavement plan of care; and
- (8.)the need for the hospice to refer the client or the client family member to appropriate health professionals for further evaluation.

§558.812 Update of the Hospice Comprehensive Assessment

- (a.) The hospice interdisciplinary team, in collaboration with a client's attending practitioner, if any, must update the client's comprehensive assessment as frequently as the condition of the client requires, but no less than every 15 days.
- (b.)The update of the comprehensive assessment must include:
 - (1.)changes that have taken place since the initial assessment;
 - (2.)information on the client's progress toward desired outcomes; and
 - (3.)a reassessment of the client's response to care.

§558.813 Hospice Client Outcome Measures

- (a.) The comprehensive assessment must include data elements that allow the hospice to measure client outcomes. The hospice must measure and document data in the same way for all clients.
- (b.)The data elements must:
 - (1.)consider aspects of care related to hospice and palliation;
 - (2.)be an integral part of the comprehensive assessment;
 - (3.)be documented by the hospice in a systematic and retrievable way for each client;
 - (4.)be used by the hospice in individual client care planning and in the coordination of a client's services; and
 - (5.)be used in the aggregate for the hospice's quality assessment and performance improvement program.

Division 3 Hospice Interdisciplinary Team, Care Planning, and Coordination of Services

§558.820 Hospice Interdisciplinary Team

- (a.) A hospice must designate an interdisciplinary team (IDT) composed of persons who work together to meet the physical, medical, psychosocial, emotional, and spiritual needs of a hospice client and family facing terminal illness and bereavement. The IDT members must provide the care and services offered by the hospice and all the members of the IDT must supervise the care and services the hospice provides.
- (b.)An IDT must include persons who are qualified and competent to practice in the following professional roles:

- (1.) a physician who is an employee or under contract with the hospice, who may also be the hospice medical director or physician designee;
 - (2.) an RN;
 - (3.) a social worker; and
 - (4.) a pastoral or other counselor.
- (c.) The hospice must designate an RN who is a member of the client's IDT to provide coordination of care and to ensure continuous assessment of the client's and family's needs and implementation of the interdisciplinary plan of care.
- (d.) A hospice may have more than one IDT. If the hospice has more than one IDT, the hospice must identify the IDT specifically designated to establish policies governing the day-to-day provision of hospice care and services.

§558.821 Hospice Plan of Care

- (a.) A hospice must designate an interdisciplinary team (IDT) to prepare a written plan of care for a client in consultation with the client's attending practitioner, if any, the client or the client's legal representative, and the primary caregiver, if any of them so desire.
- (b.) The IDT must develop an individualized written plan of care for each client. The plan of care must reflect client and family goals and interventions based on the problems identified in the initial, comprehensive, and updated comprehensive assessments.
- (c.) The hospice must provide care and services to a client and the client's family in accordance with an individualized written plan of care established by the hospice IDT.
- (d.) The client's plan of care must include all services necessary for the palliation and management of the terminal illness and related conditions. The plan of care must include:
- (1.) interventions to manage pain and symptoms;
 - (2.) a detailed statement of the scope and frequency of services necessary to meet the specific client and family needs;
 - (3.) measurable outcomes anticipated from implementing and coordinating the plan of care;
 - (4.) drugs and treatments necessary to meet the needs of the client;
 - (5.) medical supplies and equipment necessary to meet the needs of the client; and
 - (6.) the IDT's documentation, in the client record, of the client's or the client's legal representative's level of understanding, involvement, and agreement with the plan of care, in accordance with the hospice's policies.
- (e.) The hospice must ensure that the client and the client's primary caregiver receives education and training provided by hospice staff as appropriate to the client's and the client's primary caregiver's responsibilities for providing the care and services specified in the client's plan of care.

§558.822 Review of the Hospice Plan of Care

- (a.) A hospice interdisciplinary team, in collaboration with a client's attending practitioner, if any, must review, revise and document the individualized plan of care as frequently as the client's condition requires, but no less than every 15 days.
- (b.) A revised plan of care must include information from the client's updated comprehensive assessment and must note the client's progress toward outcomes and goals specified in the plan of care.

§558.823 Coordination of Services by the Hospice

In addition to the requirements in §558.288 of this chapter (relating to Coordination of Services), a hospice must develop and maintain a system of communication and integration in accordance with its written policy on coordination of services. The policy must:

- (1.) ensure that the interdisciplinary team maintains responsibility for directing, coordinating, and supervising the care and services provided to a client;
- (2.) provide for and ensure the ongoing sharing of information between all hospice personnel providing care and services in all settings, whether the care and services are provided directly or under contract; and
- (3.) provide for an ongoing sharing of information with other non-hospice health care providers furnishing services unrelated to the terminal illness and related conditions.

Division 4 Hospice Core Services

§558.830 Provision of Hospice Core Services

- (a.) A hospice must routinely provide substantially all core services directly by hospice employees in a manner consistent with accepted standards of practice. A hospice must provide the following core services:
 - (1.) physician services;
 - (2.) nursing services;
 - (3.) medical social services; and
 - (4.) counseling services.
- (b.) A hospice may contract for physician services as specified in §558.831 of this division (relating to Hospice Physician Services).
- (c.) A hospice may use contracted staff if necessary to supplement hospice employees to meet the needs of clients under extraordinary or other non-routine circumstances. A Medicare-certified hospice may also enter into a written contract with another Medicare-certified hospice to provide core services if necessary to supplement hospice employees to meet the needs of a client. The contracting hospice must maintain professional management responsibility for the services provided in accordance with §558.854 of this subchapter (relating to Hospice Professional Management Responsibility). Circumstances under which the hospice may enter into a written contract for the provision of core services include:
 - (1.) unanticipated periods of high client loads;

- (2.) staffing shortages due to illness or other short-term temporary staffing situations that could interrupt client care; and
- (3.) temporary travel of a client outside of the hospice's service area.

§558.831 Hospice Physician Services

- (a.) The hospice medical director, physician employees, and contracted physicians of the hospice, in conjunction with a client's attending practitioner, if any, are responsible for the palliation and management of a client's terminal illness and related conditions.
- (b.) A physician employee or a contracted physician must function under the supervision of the hospice medical director.
- (c.) A physician employee or a contracted physician must meet the requirement in subsection (a) of this section by either providing physician services directly or by coordinating a client's care with the attending practitioner.
- (d.) If an attending practitioner is unavailable, the medical director, a hospice physician employee, or a contracted physician is responsible for meeting the medical needs of the client.

§558.832 Hospice Nursing Services

- (a.) A hospice must provide nursing services by or under the supervision of an RN. An RN must ensure that the nursing needs of a client are met as identified in the client's initial assessment, comprehensive assessment, and updated assessments.
- (b.) An advanced practice nurse providing nursing services to a client and acting within the nurse's scope of practice may write orders for the client in accordance with a hospice's written policies and applicable State law, including the Texas Occupations Code Chapter 157, Authority of Physician to Delegate Certain Medical Acts; Texas Occupations Code Chapter 301, Nurses; and Texas Health and Safety Code Chapter 481, Texas Controlled Substances Act, and Chapter 483, Dangerous Drugs.
- (c.) A hospice may provide highly specialized nursing services under contract if the hospice provides such nursing services to a client so infrequently that providing them by a hospice employee would be impracticable and prohibitively expensive. A hospice may determine that a nursing service, such as complex wound care, infusion specialties, and pediatric nursing, is highly specialized by the nature of the service and the level of nursing skill required to be proficient in the service.

§558.833 Hospice Medical Social Services

- (a.) Medical social services must be provided to a client by a qualified social worker. A qualified hospice social worker must meet one of the following requirements:
 - (1.) active licensure in the state of Texas as a master social worker (MSW) and one year of social work experience in a health care setting; or
 - (2.) active licensure in the state of Texas as a baccalaureate social worker, one year of social work experience in a health care setting, and if employed by a hospice after December 2, 2008, must be supervised by a qualified MSW.

- (b.) A qualified licensed baccalaureate social worker employed by a hospice before December 2, 2008, is exempt from the MSW supervision requirement.
- (c.) Medical social services must be provided under the direction of a physician.
- (d.) The social work services provided must be based on:
 - (1.) the client's and family's needs as identified in the client's psychosocial assessment; and
 - (2.) the client's and family's acceptance of these services.

§558.834 Hospice Counseling Services

- (a.) Counseling services must be available to a client and family to assist the client and family in minimizing the stress and problems that arise from the terminal illness, related conditions, and the dying process.
- (b.) Counseling services must include bereavement, dietary, and spiritual counseling.
 - (1.) Bereavement counseling. Bereavement counseling means emotional, psychosocial, and spiritual support and services provided before and after the death of the client to assist with issues related to grief, loss, and adjustment. A hospice must have an organized program for the provision of bereavement services furnished under the supervision of a qualified professional with experience or education in grief or loss counseling. A hospice must:
 - (A) develop a bereavement plan of care that notes the kind of bereavement services to be offered to the client's family and other persons and the frequency of service delivery;
 - (B) make bereavement services available to a client's family and other persons in the bereavement plan of care for up to one year following the death of the client;
 - (C) extend bereavement counseling to residents of a skilled nursing facility, a nursing facility, or an intermediate care facility for individuals with an intellectual disability or related conditions when appropriate and as identified in the bereavement plan of care; and
 - (D) ensure that bereavement services reflect the needs of the bereaved.
 - (2.) Dietary counseling. Dietary counseling means education and interventions provided to a client and family regarding appropriate nutritional intake as a hospice client's condition progresses. Dietary counseling, when identified in the plan of care, must be performed by a qualified person. A qualified person includes a dietitian, nutritionist, or RN. A person that provides dietary counseling must be appropriately trained and qualified to address and assure that the specific dietary needs of a client are met.
 - (3.) Spiritual counseling. A hospice must provide spiritual counseling that meets the client's and the client's family's spiritual needs in accordance with their acceptance of this service and in a manner consistent with their beliefs and desires. A hospice must:

- (A) provide an assessment of the client's and family's spiritual needs;
- (B) make all reasonable efforts to the best of the hospice's ability to facilitate visits by local clergy, a pastoral counselor, or other persons who can support a client's spiritual needs; and
- (C) advise the client and family of the availability of spiritual counseling services.

Division 5 Hospice Non-Core Services

§558.840 Provision of Hospice Non-Core Services

- (a.) A hospice must provide the following non-core services in a manner consistent with accepted standards of practice:
 - (1.) physical therapy services;
 - (2.) occupational therapy services;
 - (3.) speech-language pathology services;
 - (4.) hospice aide and hospice homemaker services; and
 - (5.) volunteers.
- (b.) A hospice must provide non-core services directly or through a written contract.

§558.841 Physical Therapy, Occupational Therapy, and Speech-Language Pathology Services

Physical therapy services, occupational therapy services, and speech-language pathology services must be available and, when provided, offered by the hospice in a manner consistent with accepted standards of practice.

§558.842 Hospice Aide Services

- (a.) Hospice aide services must be provided by a hospice aide who meets the training and competency evaluation requirements, or the competency evaluation requirements specified in §558.843 of this division (relating to Hospice Aide Qualifications).
- (b.) A client's hospice aide services must be:
 - (1.) ordered by the designated interdisciplinary team (IDT);
 - (2.) included in the client's plan of care;
 - (3.) performed by a hospice aide in accordance with State law and applicable rules, including 22 TAC Chapter 224 (relating to Delegation of Nursing Tasks by Registered Professional Nurses to Unlicensed Personnel for Clients with Acute Conditions or in Acute Care Environments), and 22 TAC Chapter 225 (relating to RN Delegation to Unlicensed Personnel and Tasks Not Requiring Delegation in Independent Living Environments For Clients with Stable and Predictable Conditions); and
 - (4.) consistent with a hospice aide's documented training and competency skills.

- (c.) An RN who is a member of a client's designated IDT must assign a hospice aide to a specific client. An RN who is responsible for the supervision of a hospice aide, as specified in subsection (d) of this section, must prepare written client-care instructions for the hospice aide. The duties of a hospice aide include:
- (1.) providing hands-on personal care;
 - (2.) performing simple procedures as an extension of therapy or nursing services;
 - (3.) assisting with ambulation or exercises;
 - (4.) assisting with self-administered medication;
 - (5.) reporting changes in a client's medical, nursing, rehabilitative, and social needs to an RN as the changes relate to the client's plan of care and the hospice's quality assessment and improvement activities; and
 - (6.) completing client record documentation in compliance with the hospice's policies and procedures.
- (d.) An RN must make an on-site visit to a client's home to supervise the hospice aide services at least every 14 days to assess the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice IDT meet the client's needs. The hospice aide does not have to be present during this visit.
- (1.) If the RN notes an area of concern in the care provided by the aide, the RN must make an on-site visit to the location where the client is receiving care to observe and assess the hospice aide while the aide performs care.
 - (2.) If, during the on-site visit to observe the hospice aide, the RN confirms an area of concern in the aide's skills, the hospice must ensure that the aide completes a competency evaluation in accordance with §558.843 of this division.
- (e.) An RN must make an annual on-site visit to the location where a hospice client is receiving care to observe and assess each hospice aide while the aide performs care. During this on-site visit, the RN must assess the aide's ability to demonstrate initial and continued satisfactory performance in meeting outcome criteria including:
- (1.) following the client's plan of care for completion of tasks assigned to the hospice aide by an RN;
 - (2.) creating successful interpersonal relationships with the client and the client's family;
 - (3.) demonstrating competency with assigned tasks;
 - (4.) complying with infection control policies and procedures; and
 - (5.) reporting changes in the client's condition.

§558.843 Hospice Aide Qualifications

- (a.) A hospice must use a qualified hospice aide to provide hospice aide services. A qualified hospice aide is a person who has successfully completed:
- (1.) a training program and competency evaluation program that complies with the requirements in subsections (c) and (d) of this section; or

- (2.) a competency evaluation program that complies with the requirements in subsection (d) of this section.
- (b.) A person who has not provided home health or hospice aide services for compensation in an agency during the most recent continuous period of 24 consecutive months must successfully complete the programs described in subsection (a)(1) of this section or the program described in subsection (a)(2) of this section before providing hospice aide services.
- (c.) A hospice aide training program must address each of the subject areas listed in paragraph (1) of this subsection through classroom and supervised practical training totaling at least 75 hours. At least 16 hours must be devoted to supervised practical training. At least 16 hours of classroom training must be completed before the supervised practical training begins.
- (1.) Subject areas that must be addressed in a hospice aide training program include:
- (A) communication skills, including the ability to read, write, and verbally report clinical information to clients, caregivers, and other hospice staff;
 - (B) observation, reporting, and documentation of a client's status and the care or service provided;
 - (C) reading and recording temperature, pulse, and respiration;
 - (D) basic infection control procedures;
 - (E) basic elements of body functioning and changes in body function that must be reported to an aide's supervisor;
 - (F) maintenance of a clean, safe, and healthy environment;
 - (G) recognizing emergencies and the knowledge of emergency procedures and their application;
 - (H) the physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for a client and his or her privacy and property;
 - (I) appropriate and safe techniques for performing personal hygiene and grooming tasks, including:
 - (i) bed bath;
 - (ii) sponge, tub, and shower bath;
 - (iii) hair shampoo in sink, tub, and bed;
 - (iv) nail and skin care;
 - (v) oral hygiene; andtoileting and elimination;
 - (J) safe transfer techniques and ambulation;
 - (K) normal range of motion and positioning;

(L) adequate nutrition and fluid intake; and

(M) other tasks that the hospice may choose to have an aide perform. The hospice must train hospice aides, as needed, for skills not listed in subparagraph (I) of this paragraph.

(2.) The classroom training of hospice aides and the supervision of hospice aides during supervised practical training must be conducted by or under the general supervision of an RN who possesses a minimum of two years of nursing experience, at least one of which must be in the provision of home health or hospice care. Other persons, such as a physical therapist, occupational therapist, medical social worker, and speech-language pathologist may be used to provide instruction under the supervision of a qualified RN who maintains overall responsibility for the training.

(3.) An agency must maintain documentation that demonstrates that its hospice aide training program meets the requirements in this subsection. Documentation must include a description of how additional skills, beyond the basic skills listed in paragraph (1) of this subsection, are taught and tested if the agency requires a hospice aide to perform more complex tasks.

(d.) A hospice aide competency evaluation program must address each of the subject areas listed in paragraphs (2) and (3) of this subsection.

(1.) An RN, in consultation with the other persons described in subsection (c)(2) of this section, must perform the competency evaluation.

(2.) The RN must observe and evaluate the hospice aide's performance of tasks with a client in the following areas:

(A) communication skills, including the ability to read, write, and verbally report clinical information to clients, caregivers, and other hospice staff;

(B) reading and recording temperature, pulse, and respiration;

(C) appropriate and safe techniques for performing personal hygiene and grooming tasks, including:

(i) bed bath;

(ii) sponge, tub, and shower bath;

(iii) hair shampoo in sink, tub, and bed;

(iv) nail and skin care;

(v) oral hygiene; and

(vi) toileting and elimination;

(D) safe transfer techniques and ambulation; and

(E) normal range of motion and positioning.

(3.) The RN must evaluate a hospice aide's performance of each of the tasks listed in this paragraph by requiring the aide to submit to a written examination, an oral

examination, or by observing the hospice aide's performance with a client. The tasks must include:

- (A) observing, reporting, and documenting client status and the care or service provided;
- (B) basic infection control procedures;
- (C) basic elements of body functioning and changes in body function that must be reported to an aide's supervisor;
- (D) maintaining a clean, safe, and healthy environment;
- (E) recognizing emergencies and knowing emergency procedures and their application;
- (F) the physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for a client and his or her privacy and property;
- (G) adequate nutrition and fluid intake; and
- (H) other tasks the hospice may choose to have the hospice aide perform. The hospice must evaluate the competency of a hospice aide, as needed, for skills not listed in paragraph (2)(C) of this subsection.

(4.) A hospice aide has not successfully completed a competency evaluation program if the aide has an unsatisfactory rating in more than one subject area listed in paragraphs (2) and (3) of this subsection.

(5.) If a hospice aide receives an unsatisfactory rating in any of the subject areas listed in paragraphs (2) and (3) of this subsection, the aide must not perform that task without direct supervision by an RN until after:

- (A) the aide receives training in the task for which the aide was evaluated as unsatisfactory; and
- (B) successfully completes a subsequent competency evaluation with a satisfactory rating on the task.

(6.) An agency must maintain documentation that its hospice aide competency evaluation program meets the requirements in this subsection. The agency's documentation of a hospice aide's competency evaluation must demonstrate the aide's competency to provide services to a client that exceed the basic skills taught and tested before the aide is assigned to care for a client who requires more complex services.

(e.) A hospice aide must receive at least 12 hours of in-service training during each 12-month period. The agency may provide the 12 hours of in-service training during the 12-month calendar year, or within 12 months after a hospice aide's employment or contract anniversary date.

(1.) The in-service training must be supervised by an RN.

(2.) An agency may provide hospice aide in-service training supervised by an RN while the aide is providing care to a client. The RN must document the exact new

skill or theory taught in the client's residence and the duration of the training. The in-service training provided in a client's residence must not be a repetition of a hospice aide's competency in a basic skill.

- (3.) An agency must maintain documentation that demonstrates the agency meets the hospice aide in-service training requirements in this subsection.
- (f.) An agency that hires or contracts to use a hospice aide who completes a training program and competency evaluation program, or a competency evaluation program provided by another agency or a person who is not licensed as an agency must ensure that the programs or program completed comply with the requirements in subsection (c) and (d) of this section.
- (g.) A Medicare-certified hospice agency must also comply with 42 CFR §418.76(b) and 42 CFR §418.76(f).

§558.844 Hospice Homemaker Services

- (a.) Homemaker services must be provided by a qualified hospice homemaker as described in §558.845 of this division (relating to Hospice Homemaker Qualifications).
- (b.) A member of a client's designated interdisciplinary team (IDT) must coordinate and supervise the homemaker services provided and prepare written instructions for the duties a hospice homemaker performs.
- (c.) Hospice homemaker services may include assistance in maintaining a safe and healthy environment and services to enable the client and the client's family to carry out the hospice treatment plan. Hospice homemaker services do not include providing personal care or any hands-on services.
- (d.) A hospice homemaker must report all concerns about a client or the client's family to the member of the IDT responsible for coordinating the hospice homemaker services.

§558.845 Hospice Homemaker Qualifications

- (a.) A hospice must use a qualified hospice homemaker to provide hospice homemaker services. A qualified hospice homemaker is a person who:
 - (1.) successfully completes an agency's hospice orientation and training as specified in subsection (b) of this section; or
 - (2.) is a qualified hospice aide as described in §558.843 of this division (relating to Hospice Aide Qualifications).
- (b.) The orientation for a hospice homemaker must address the needs and concerns of a client and a client's family who are coping with a terminal illness. The training for a hospice homemaker must include:
 - (1.) assisting in maintaining a safe and healthy environment for a client and the client's family; and
 - (2.) providing homemaker services to help the client and the client's family to carry out the treatment plan.

- (c.) If there is a direct conflict between the requirements of this chapter and federal regulations, the requirements that are more stringent apply to a Medicare-certified hospice agency.

§558.846 Services Provided Under a State Medicaid Personal Care Benefit

- (a.) If a client receives services under a state Medicaid personal care benefit, a hospice may use the services provided under the Medicaid personal care benefit to the extent the hospice would routinely use the services of a hospice client's family in implementing the client's plan of care.
- (b.) The hospice must coordinate its hospice aide and homemaker services with the Medicaid personal care benefit to ensure that the client receives the hospice aide and homemaker services the client needs.

Division 6 Hospice Organization and Administration of Services

§558.850 Organization and Administration of Hospice Services

- (a.) A hospice must organize, manage, and administer its hospice program to provide hospice care and support services to a client, the client's caregivers, and the client's family that are necessary for the palliation and management of a client's terminal illness and related conditions. A hospice must provide hospice care and support services that:
 - (1.) optimize the client's comfort and dignity; and
 - (2.) are consistent with the client's and the client's family's needs and goals with priority given to the client's needs and goals.
- (b.) Hospice services may be provided in the client's residence or independent living environment and, when needed, in a hospice inpatient unit or in a Medicare/Medicaid-certified facility where the hospice makes inpatient care available under arrangement.
- (c.) A hospice must be primarily engaged in providing the following care and services and must do so in a manner that is consistent with accepted standards of practice:
 - (1.) physician services;
 - (2.) nursing services;
 - (3.) medical social services;
 - (4.) counseling services, including bereavement, dietary, and spiritual counseling;
 - (5.) physical therapy, occupational therapy, and speech-language pathology services;
 - (6.) hospice aide and hospice homemaker services;
 - (7.) volunteer services;
 - (8.) short-term inpatient care; and
 - (9.) medical supplies and appliances, durable medical equipment, and drugs and biologicals.
- (d.) A hospice must make the following services routinely available 24 hours a day, seven days a week:
 - (1.) nursing services;

- (2.)physician services; and
- (3.)drugs and biologicals.
- (e.) A hospice must make the following services available 24 hours a day when reasonable and necessary to meet the client's and the client's family's needs:
 - (1.)medical social services;
 - (2.)counseling services, including bereavement, dietary, and spiritual counseling;
 - (3.)physical therapy, occupational therapy, and speech-language pathology services;
 - (4.)hospice aide and hospice homemaker services;
 - (5.)volunteer services;
 - (6.)short-term inpatient care; and
 - (7.)medical supplies and appliances and durable medical equipment.
- (f.) A Medicare-certified hospice may not discontinue or reduce care provided to a Medicare or Medicaid beneficiary because of the beneficiary's inability to pay for the care.

§558.851 Hospice Services Provided by a Licensed Person

- (a.) Services provided by a licensed person directly or under contract by a hospice must be authorized, delivered, and supervised only by a qualified licensed person who practices under the hospice's policies and procedures. For the purpose of this section, services provided by a licensed person include skilled nursing care, physical therapy, occupational therapy, speech language pathology, and medical social services.
- (b.) A licensed person providing hospice services directly or under contract must:
 - (1.)actively participate in the coordination of all aspects of a client's hospice care, in accordance with accepted standards of practice, including participating in ongoing interdisciplinary comprehensive assessments, developing and evaluating the plan of care, and contributing to client and family counseling and education; and
 - (2.)participate in the hospice's quality assessment and performance improvement program and hospice-sponsored in-service training.

§558.852 Hospice Governing Body and Administrator

- (a.) The hospice must have a governing body that assumes full legal authority and responsibility for the management of the hospice, the provision of all hospice services, its fiscal operations, and continuous quality assessment and performance improvement.
- (b.) The governing body must appoint an administrator who:
 - (1.)meets the qualifications and conditions specified in §558.244(a)(1) and (2) of this chapter (relating to Administrator Qualifications and Conditions and Supervising Nurse Qualifications); and
 - (2.)reports to the governing body or persons serving as the governing body.

§558.853 Hospice Infection Control Program

- (a.) In addition to the requirements in §558.285 of this chapter (relating to Infection Control), a hospice must maintain an effective infection control program that protects clients, families, visitors, and hospice personnel by preventing and controlling infections and communicable diseases.
- (b.) A hospice must follow accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.
- (c.) A hospice must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the hospice's quality assessment and performance improvement program. The infection control program must include:
 - (1.) a method of identifying infectious and communicable disease problems; and
 - (2.) a plan for implementing the appropriate actions that are expected to result in improvement and disease prevention.
- (d.) A hospice must provide infection control education to employees, volunteers, contract staff, clients, and family members and other caregivers.

§558.854 Hospice Professional Management Responsibility

- (a.) A hospice that has a written contract with another agency, person, or organization to furnish services must retain administrative and financial management and oversight of staff and services for all contracted services to ensure the provision of quality care.
- (b.) In addition to the requirements in §558.289 of this chapter (relating to Independent Contractors and Arranged Services), a hospice's written contracts must require that all services are:
 - (1.) authorized by the hospice;
 - (2.) furnished in a safe and effective manner by qualified personnel; and
 - (3.) delivered in accordance with a client's plan of care.

§558.855 Criminal Background Checks

- (a.) In addition to the requirements in §558.247 of this chapter (relating to Verification of Employability and Use of Unlicensed Persons), a hospice must conduct a criminal history check on all hospice employees and volunteers with direct client contact or access to client records to verify each employee's or volunteer's criminal history report does not include a conviction that bars employment under Texas Health and Safety Code §250.006, or a conviction that the hospice determines is a contraindication to employment.
- (b.) In addition to the requirements in §558.289 of this chapter (relating to Independent Contractors and Arranged Services), hospice contracts to provide inpatient care must require that all contracted entities conduct a criminal history check on contracted staff who have direct client contact or access to client records to verify each contract staff's criminal history report does not include a conviction that bars employment under Texas Health and Safety Code §250.006

§558.856 Hospice Alternate Delivery Sites

- (a.) If a hospice operates an ADS, the hospice must comply with this section.
- (b.) A Medicare-certified hospice agency must have an ADS approved by CMS before providing Medicare-reimbursed hospice services to Medicare clients from the ADS.
- (c.) An ADS must be part of the hospice and must share administration, supervision, and services with the parent agency.
- (d.) In addition to the requirements in §558.242 of this chapter (relating to Organizational Structure and Lines of Authority), the lines of authority and professional and administrative control must be clearly delineated in the hospice's organizational structure and in practice and must be traced to the parent agency.
- (e.) The hospice must continually monitor and manage all services provided by its ADS to ensure that services are delivered in a safe and effective manner and to ensure that a client and the client's family receives the necessary care and services outlined in the plan of care.

§558.857 Hospice Staff Training

In addition to the requirements in §558.245 of this chapter (relating to Staffing Policies), a hospice must:

- (1.) provide orientation about the hospice philosophy, and about supportive palliative care, to all employees and contracted staff who have client and family contact;
- (2.) provide an initial orientation for an employee that addresses the employee's specific job duties;
- (3.) assess the skills and competence of all persons furnishing care, including volunteers furnishing services, and, as necessary, provide in-service training and education programs where required;
- (4.) have written policies and procedures describing its methods for assessing competency; and
- (5.) maintain a written description of the in-service training provided during the previous 12 months.

§558.858 Hospice Medical Director

- (a.) A hospice must designate in writing one physician to serve as its medical director. The medical director must be a doctor of medicine or osteopathy who is an employee or under contract with the hospice. The medical director may also be a volunteer physician under the control of the hospice.
- (b.) A hospice must designate in writing a physician designee to assume the same responsibilities and obligations as the medical director when the medical director is not available.
- (c.) A hospice may contract for a physician to serve as its medical director with either a self-employed physician or a physician employed by a professional entity or physicians group. The contract for medical director services must specify the name of the physician who assumes the medical director responsibilities and obligations.

- (d.) The medical director or physician designee assumes responsibility for the medical component of a hospice's client care program.
- (e.) The medical director or physician designee must review a client's clinical information and provide written initial certification that the client's life expectancy is anticipated to be six months or less if the client's terminal illness runs its normal course.
- (f.) Before each recertification period for the client, the medical director or physician designee must review the client's clinical information and provide written recertification of the client's terminal illness.
- (g.) When determining the client's life expectancy is six months or less, the medical director or physician designee must consider:
 - (1.) the primary terminal condition;
 - (2.) related diagnoses, if any;
 - (3.) current subjective and objective medical findings;
 - (4.) current medication and treatment orders; and
 - (5.) information about the medical management of any of the client's conditions unrelated to the terminal illness.

§558.859 Hospice Discharge or Transfer of Care

- (a.) If a hospice transfers the care of a client to another facility or agency, the hospice must provide a copy of the hospice discharge summary and, if requested, a copy of the client's record to the receiving facility or agency.
- (b.) If a client revokes the election of hospice care or is discharged by the hospice for any reason listed in subsection (d) of this section, the hospice must provide a copy of the hospice discharge summary and, if requested, a copy of the client's record to the client's attending practitioner.
- (c.) A hospice discharge summary must include:
 - (1.) a summary of the client's stay, including treatments, symptoms, and pain management;
 - (2.) the client's current plan of care;
 - (3.) the client's latest physician orders; and
 - (4.) any other documentation needed to assist in post-discharge continuity of care or that is requested by the attending practitioner or receiving facility or agency.
- (d.) In addition to the requirements in §558.295 of this chapter (relating to Client Transfer or Discharge Notification Requirements), a hospice may discharge a client if:
 - (1.) the client moves out of the hospice's service area or transfers to another hospice;
 - (2.) the hospice determines that the client is no longer terminally ill; or
 - (3.) the hospice determines, under a policy set by the hospice for addressing discharge for cause, that the behavior of the client or other person in the client's home is

disruptive, abusive, or uncooperative to the extent that delivery of care to the client or the ability of the hospice to operate effectively is seriously impaired.

- (e.) Before a hospice seeks to discharge a client for cause, the hospice must:
 - (1.) advise the client that a discharge for cause is being considered;
 - (2.) make a reasonable effort to resolve the problems presented by the client's behavior or situation;
 - (3.) document in the client's record the problems and efforts made by the hospice to resolve the problems; and
 - (4.) ascertain that the client's proposed discharge is not due to the client's use of necessary hospice services.
- (f.) Before discharging a client for any reason listed in subsection (d) of this section, the hospice must obtain a written physician's discharge order from the hospice medical director. If the client has an attending practitioner involved in the client's care, the attending practitioner should be consulted before discharge and the practitioner's review and decision should be included in the discharge note.
- (g.) A hospice must have a discharge planning process that addresses the possibility that a client's condition might stabilize or otherwise change such that the client cannot continue to be certified as terminally ill. A client's discharge planning must include any necessary family counseling, client education or other services before the hospice discharges the client based on a decision by the hospice medical director or physician designee that the client is no longer terminally ill.

§558.860 Provision of Medical Supplies, and Durable Medical Equipment by a Hospice

- (a.) While a client is under hospice care, a hospice must provide medical supplies and appliances as well as durable medical equipment related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care.
- (b.) A hospice must ensure that manufacturer recommendations for performing routine and preventive maintenance on durable medical equipment are followed. The equipment must be safe, and work as intended for use in the client's environment. Where a manufacturer recommendation for a piece of equipment does not exist, the hospice must ensure that repair and routine maintenance policies are developed. The hospice may use persons under contract to ensure the maintenance and repair of durable medical equipment.
- (c.) A hospice must ensure that a client, where appropriate, as well as the family or other caregivers, receive instruction in the safe use of durable medical equipment and supplies. The hospice may use persons under contract to ensure client and family instruction. The client, family, or caregiver must be able to demonstrate the appropriate use of durable medical equipment to the satisfaction of the hospice staff.
- (d.) A hospice may only contract for durable medical equipment services with a durable medical equipment supplier that meets the Medicare standards for durable medical equipment, prosthetics, orthotics, and supplies suppliers at 42 CFR §424.57.

§558.861 Management of Drugs and Biologicals and Disposal of Controlled Substance Prescription Drugs in a Client's Home or Community Setting

- (a.) While a client is under hospice care, a hospice must provide drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care.
- (b.) A hospice must ensure that the interdisciplinary team (IDT) confers with a person with education and training in drug management, as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet a client's needs. The hospice must be able to demonstrate that the person has specific education and training in drug management. Persons with education and training in drug management include:
 - (1.) a licensed pharmacist, a physician who is board certified in hospice and palliative medicine, or an RN who is certified in palliative nursing; or
 - (2.) a physician, an RN, or an advanced practice nurse who completes a specific drug management course for hospice or palliation.
- (c.) Only a physician or an advanced practice nurse, in accordance with the plan of care, may order drugs for a client.
- (d.) If the drug order is verbal or given by or through electronic transmission:
 - (1.) it must be given only to a licensed nurse, pharmacist, or physician; and
 - (2.) the person receiving the order must record and sign it immediately and have the prescribing person sign it in accordance with the agency's policies and applicable State and federal regulations.
- (e.) A hospice must obtain drugs and biologicals from community or institutional pharmacists or stock drugs and biologicals itself. A hospice that dispenses, stores, and transports drugs must do so in accordance with federal, State, and local laws and regulations, as well as the hospice's own policies and procedures. A hospice that operates its own pharmacy must comply with the Texas Occupations Code, Subtitle J, and applicable pharmacy and pharmacists' regulations adopted by the Texas Board of Pharmacy under that subtitle.
- (f.) The IDT, as part of the review of the plan of care, must determine the ability of the client or the client's family to safely administer drugs and biologicals to the client in the client's home.
- (g.) Drugs and biologicals must be labeled in accordance with currently accepted professional practice and must include appropriate usage and cautionary instructions, as well as an expiration date, if applicable.
- (h.) A hospice must have written policies and procedures for the safe use and storage of drugs and biologicals in a client's home.
- (i.) A hospice must have written policies and procedures that address management of controlled substance prescription drugs in a client's home, including:
 - (1.) at the time when controlled substance prescription drugs are first ordered;

- (2.)when controlled substance prescription drugs are discontinued;
 - (3.)when a new controlled substance prescription drug is ordered; and
 - (4.)when the client dies.
- (j.) At the time when controlled substance prescription drugs are first ordered for use in a client's home, the hospice must:
- (1.)provide a copy of the hospice's written policies and procedures on the management of controlled substance prescription drugs in a client's home to the client or client representative and family;
 - (2.)discuss the hospice policies and procedures for managing the safe use of controlled substance prescription drugs with the client or LAR and the family in a language and manner that they understand, to ensure that these parties are educated regarding the safe use, storage, and disposal of controlled substance prescription drugs in the client's home; and
 - (3.)document in the client record that the hospice provided and discussed its written policies and procedures for managing the safe use and storage of controlled substance prescription drugs in the client's home, as described in subsection (m) of this section.
- (k.) A hospice must have a written policy describing whether the agency will dispose of a client's unused controlled substance prescription drugs on the client's death or in other circumstances in which disposal is appropriate, as described in subsection (m) of this section.
- (l.) If a hospice agency's policy under subsection (k) of this section provides that the agency will dispose of a client's unused controlled substance prescription drugs as described in that subsection, the written policies and procedures which the hospice must implement and enforce, must:
- (1.)identify disposal methods that are consistent with recommendations by the United States Food and Drug Administration and the laws of the State of Texas;
 - (2.)permit disposal described in subsection (k) of this section only by a hospice employee or contractor who is a health care practitioner licensed to perform medical or nursing services who meets the conditions of this section;
 - (3.)require each health care practitioner responsible for disposal of an unused controlled substance of a client under this section to receive training regarding the secure and responsible disposal of controlled substance prescription drugs in accordance with paragraph (1) of this subsection and in a manner that discourages abuse, misuse, or diversion;
 - (4.)require that hospice agency staff:
 - (A) provide a copy of the disposal policies and procedures to a licensed facility in which the client is residing or receiving short-term in-patient hospice services;

- (B) provide a copy of the disposal policies and procedures to the client and the client's family;
 - (C) discuss the policies and procedures with the patient and the client's family in a language and manner the client and client's family understand;
 - (D) document in the client's clinical record that the policies and procedures were provided and discussed as required by subsections (b) and (c) of this section; and
 - (E) document the client's agreement to the disposal of the client's unused controlled substance prescription drugs under circumstances described in subsection (m) of this section by a qualified health practitioner employed or contracted by the agency; and
- (5.) otherwise comply with state, federal, and local laws applicable to the disposal of drugs and biologicals in a facility.
- (m.) A health care practitioner qualified under subsection (l) of this section may confiscate and dispose of a client's unused controlled substance prescription drug if:
- (1.) the client has died;
 - (2.) the drug has expired; or
 - (3.) the client's physician has given written instructions that the patient should no longer use the drug.
- (n.) A hospice agency may not dispose of controlled prescription drugs not prescribed to the client.
- (o.) A health care practitioner qualified under subsection (l) of this section, confiscating the controlled substance prescription drug, must dispose of the drug in a manner consistent with recommendations of the United States Food and Drug Administration and the laws of the State of Texas.
- (p.) A health care practitioner qualified under subsection (l) of this section must dispose of a client's unused controlled substance prescription drugs as described in this section only at the location at which practitioner confiscated the drug.
- (q.) A health care practitioner disposal of a client's unused controlled substance prescription drugs as described in this section must be witnessed by another person 18 years of age or older. The witness does not have to be a hospice employee.
- (r.) After disposing of the client's unused controlled substance prescription drug, the health care practitioner shall document in the client's record:
- (1.) The name of the drug;
 - (2.) the dosage of the drug the client was receiving;
 - (3.) the route of controlled substance prescription drug administration;
 - (4.) the quantity of the controlled substance prescription drug originally dispensed and the quantity of the drug remaining;
 - (5.) the time, date, and manner of disposal; and

name and relationship of the witness to the client.

- (s.) A health care practitioner shall document in the client's file if a family member of the client prevented the confiscation and disposal of a controlled substance prescription drug authorized under this section.
- (t.) A health care practitioner shall document in the client's file if an employee of a licensed facility where the client is receiving in-patient hospice services prevented the confiscation and disposal of a controlled substance prescription drug otherwise authorized under this section.

§558.862 Management of Drugs and Biologicals and Disposal of Controlled Substance Prescription Drugs in an Inpatient Hospice Unit

- (a.) The requirements stated in §558.861(a)-(g) of this division (relating to Management of Drugs and Biologicals and Disposal of Controlled Substance Prescription Drugs in a Client's Home or Community Setting) also apply to a hospice that provides inpatient care directly in its own inpatient unit.
- (b.) A hospice that provides inpatient care directly in its own inpatient unit must provide pharmaceutical services under the direction of a qualified licensed pharmacist who is an employee of or under contract with the hospice. The services provided by the pharmacist must include evaluation of a client's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.
- (c.) A hospice that provides inpatient care directly in its own inpatient unit must:
 - (1.) have a written policy in place that promotes dispensing accuracy; and
 - (2.) maintain current and accurate records of the receipt and disposition of all controlled drugs.
- (d.) Clients receiving care in a hospice inpatient unit may only be administered medications by the following persons:
 - (1.) a licensed nurse, physician, or other health care professional in accordance with their scope of practice and State law;
 - (2.) a home health medication aide; or
 - (3.) a client, upon approval by the interdisciplinary team.
- (e.) A hospice that provides inpatient care directly in its own inpatient unit must comply with the following additional requirements.
 - (1.) All drugs and biologicals must be stored in secure areas. All controlled drugs listed in Schedules II, III, IV, and V, established under 21 United States Code §812, must be stored in locked compartments within such secure storage areas. Only personnel authorized to administer controlled drugs as noted in subsection (i) of this section may have access to the locked compartments.
 - (2.) Discrepancies in the acquisition, storage, dispensing, administration, disposal, or return of controlled drugs must be investigated immediately by the pharmacist and hospice administrator and reported, without limitation, to the United States Department of Justice, Drug Enforcement Administration, Diversion Control

Division. A hospice must maintain a written account of its investigation and make it available to State and federal officials if requested.

- (f.) A hospice that provides inpatient care directly in its own inpatient unit must dispose of controlled drugs in compliance with the hospice's policy and in accordance with State and federal requirements, including Texas Health and Safety Code Chapter 481. The hospice must maintain current and accurate records of the receipt and disposition of all controlled drugs.

§558.863 Hospice Short-term Inpatient Care

- (a.) A hospice must make inpatient care available when needed for pain control, symptom management, and respite purposes.
- (b.) A hospice must ensure that inpatient care for pain control and symptom management is provided in either:
 - (1.) a hospice inpatient unit that meets the additional standards in Division 7 of this subchapter (relating to Hospice Inpatient Units) and the Medicare Conditions of Participation for providing inpatient care directly as specified in 42 CFR §418.110; or
 - (2.) a Medicare-certified hospital or skilled nursing facility that also meets:
 - (A) the licensing standards specified in §558.870(b)(1) and (2) of this subchapter (relating to Staffing in a Hospice Inpatient Unit) regarding 24-hour nursing services, and in §558.871(d)(1)-(4) of this subchapter (relating to Physical Environment in a Hospice Inpatient Unit); and
 - (B) the federal Medicare standards specified in 42 CFR §418.110(b) and (e) regarding 24-hour nursing services and patient areas.
- (c.) A hospice must ensure that inpatient care for respite purposes is provided either by:
 - (1.) a facility specified in subsection (b)(1) or (2) of this section; or
 - (2.) a Medicare-certified or Medicaid-certified nursing facility that also meets the licensing standards specified in §558.871(d)(1)-(4) of this subchapter regarding client areas and the federal Medicare standards specified in 42 CFR §418.110(e) regarding patient areas.
- (d.) A facility providing respite care must provide 24-hour nursing services that meet the nursing needs of all clients and are furnished in accordance with each client's plan of care. Each client must receive all nursing services as prescribed and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.
- (e.) In addition to the requirements in §558.289(b) of this chapter (relating to Independent Contractors and Arranged Services), if a hospice has an agreement with a facility to provide for inpatient care, there must be a written contract coordinated by the hospice that specifies that:
 - (1.) the hospice supplies the facility with a copy of the client's plan of care and specifies the inpatient services to be furnished;

- (2.)the facility has established client care policies consistent with those of the hospice and agrees to abide by the plan of care established by the hospice for each client and to follow the hospice agency's protocols for supporting optimal quality of life for its clients;
- (3.)the facility's clinical record for a hospice client includes documentation of all inpatient services furnished and events regarding care that occurred at the facility;
- (4.)a copy of the discharge summary be provided to the hospice at the time of discharge;
- (5.)a copy of the inpatient clinical record is available to the hospice at the time of discharge;
- (6.)the facility has identified a person within the facility who is responsible for the implementation of the provisions of the agreement;
- (7.)the hospice retains responsibility for ensuring that the training of personnel who will be providing the client's care in the facility has been provided and that a description of the training and the names of those giving the training are documented; and
- (8.)a method for verifying that the requirements in paragraphs (1) - (7) of this subsection are met.

Division 7 Hospice Inpatient Units

§558.870 Staffing in a Hospice Inpatient Unit

- (a.) A hospice is responsible for staffing its inpatient unit with the numbers and types of qualified, trained, and experienced staff to meet the care needs of every client in the inpatient unit to ensure that plan of care outcomes are achieved and negative outcomes are avoided.
- (b.) A hospice inpatient unit must provide 24-hour nursing services that meet the nursing needs of all clients and are furnished in accordance with each client's plan of care.
 - (1.)A client must receive all nursing services as prescribed in the plan of care and must be kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.
 - (2.)If at least one client in the hospice inpatient unit is receiving general inpatient care for pain control or symptom management, then each shift must include an RN who provides direct client care.
 - (3.)A hospice inpatient unit must have a nurse call system. The hospice must install in a client's room a system that:
 - (A) is equipped with an easily activated, functioning device accessible to the client; and
 - (B) allows the client to call for assistance from a staff person on the unit.

§558.871 Physical Environment in a Hospice Inpatient Unit

(a.) Safety Management. A hospice inpatient unit must maintain a safe physical environment free of hazards for clients, staff, and visitors.

(1.) A hospice inpatient unit must address real or potential threats to the health and safety of the clients, others, and property.

(2.) In addition to §558.256 of this chapter (relating to Emergency Preparedness Planning and Implementation), a hospice inpatient unit must have a written disaster preparedness plan that addresses the core functions of emergency management as described in subparagraphs (A) - (G) of this paragraph. The facility must maintain documentation of compliance with this paragraph.

(A) The portion of the plan on direction and control must:

- (i) designate a person by position, and at least one alternate, to be in charge during implementation of an emergency response plan, with authority to execute a plan to evacuate or shelter in place;
- (ii) include procedures the facility will use to maintain continuous leadership and authority in key positions;
- (iii) include procedures the facility will use to activate a timely response plan based on the types of disasters identified in the risk assessment;
- (iv) include procedures the facility will use to meet staffing requirements;
- (v) include procedures the facility will use to warn or notify facility staff about internal and external disasters, including during off hours, weekends, and holidays;
- (vi) include procedures the facility will use to maintain a current list of who the hospice will notify once warning of a disaster is received;
- (vii) include procedures the facility will use to alert critical facility personnel once a disaster is identified; and
- (viii) include procedures the facility will use to maintain a current 24-hour contact list for all personnel.

(B) The portion of the plan on communication must include procedures:

- (i) for continued communication, including procedures during an evacuation to maintain contact with critical personnel and with all vehicles traveling in an evacuation caravan;
- (ii) to maintain an accessible, current list of the phone numbers of:

- I. client family members;
- II. local shelters;
- III. prearranged receiving facilities;
- IV. the local emergency management agencies;
- V. other health care providers; and
- VI. State and federal emergency management agencies;

(iii) to notify staff, clients, families of clients, families of critical staff, prearranged receiving facilities, and others of an evacuation or the plan to shelter in place;

(iv) to provide a contact number for out-of-town family members to call for information; and

(v) to relocate and track clients during disasters that require mass evacuations.

(C) The portion of the plan on resource management must include procedures:

(i) to maintain contracts and agreements with vendors as needed to ensure the availability of the supplies and transportation needed to execute the plan to shelter in place or evacuate;

(ii) to develop accurate, detailed, and current checklists of essential supplies, staff, equipment, and medications;

(iii) to designate responsibility for completing the checklists during disaster operations;

(iv) for the safe and secure transportation of adequate amounts of food, water, medications, and critical supplies and equipment during an evacuation; and

(v) to maintain a supply of sufficient resources for at least seven days to shelter in place, which must include:

- I. emergency power, including backup generators and accounts for maintaining a supply of fuel;
- II. potable water in an amount based on population and location;
- III. the types and amounts of food for the number and types of clients served;
- IV. extra pharmacy stocks of common medications; and
- V. extra medical supplies and equipment, such as oxygen, linens, and any other vital equipment.

(D) The portion of the plan on sheltering in place must:

- (i) be developed using information about the building's construction and Life Safety Code (LSC) systems;
- (ii) describe the criteria to be used to decide whether to shelter in place versus evacuate;
- (iii) include procedures to assess whether the building is strong enough to withstand the various types of possible disasters and to identify the safest areas of the building;
- (iv) include procedures to secure the building against damage;
- (v) include procedures for collaborating with the local emergency management agencies regarding the decision to shelter in place;
- (vi) include procedures to assign each task in the sheltering plan to facility staff;
- (vii) describe procedures to shelter in place that allow the facility to maintain 24-hour operations for a minimum of seven days to maintain continuity of care for the number and types of clients served; and
- (viii) include procedures to provide for building security.

(E) The portion of the plan on evacuation must:

- (i) include contracts with prearranged receiving facilities, including a hospice inpatient facility, skilled nursing facility, nursing facility, assisted living facility, or hospital, with at least one facility located at least 50 miles away;
- (ii) include procedures to identify and follow evacuation and alternative routes for transporting clients to a receiving facility and to notify the proper authorities of the decision to evacuate;
- (iii) include procedures to protect and transport client records and to match them to each client;
- (iv) include procedures to maintain a checklist of items to be transported with clients, including medications and assistive devices, and how the items will be matched to each client;
- (v) include staffing procedures the facility will use to ensure that staff accompanies evacuating clients when the hospice transports clients to a receiving facility;
- (vi) include procedures to identify and assign staff responsibilities, including how clients will be cared for during evacuations and a backup plan for lack of sufficient staff;

- (vii) include procedures facility staff will use to account for all persons in the building during the evacuation and to track all persons evacuated;
- (viii) include procedures for the use, protection, and security of the identifying information the facility will use to identify evacuated clients;
- (ix) include procedures facility staff will follow if a client becomes ill or dies in route when the hospice transports clients to a receiving facility;
- (x) include procedures to make a hospice counselor available when staff accompanies clients during transport by the hospice to a receiving facility;
- (xi) include the facility's policy on whether family of staff and clients can shelter at the hospice and evacuate with staff and clients;
- (xii) include procedures to coordinate building security with the local emergency management agencies;
- (xiii) include procedures facility staff will use to determine when it is safe to return to the geographical area;
- (xiv) include procedures facility staff will use to determine if the building is safe for reoccupation; and
- (xv) be approved by the local emergency management coordinator (EMC) at least annually and when updated.

(F) The portion of the plan on transportation must:

- (i) describe how the hospice prearranges for a sufficient number of vehicles to provide suitable, safe transportation for the type and number of clients being served; and
- (ii) include procedures to contact the local EMC to coordinate the facility's transportation needs in the event its prearrangements for transportation fail for reasons beyond the facility's control.

(G) The portion of the plan on training must include:

- (i) procedures that specify when and how the disaster response plan is reviewed with clients and family members;
- (ii) procedures to review the role and responsibility of a client able to participate with the plan;

- (iii) procedures for initial and periodic training for all facility staff to carry out the plan;
- (iv) the frequency for conducting disaster drills and demonstrations to ensure staff are fully trained with respect to their duties under the plan; and
- (v) procedures to conduct emergency response drills at least annually either in response to an actual disaster or in a planned drill, which may be in addition to or combined with the drills required by the LSC as specified in subsection (c)(1) of this section.

(b.) Physical plant and equipment. A hospice must develop procedures for controlling the reliability and quality of:

- (1.) the routine storage and prompt disposal of trash and medical waste;
- (2.) light, temperature, and ventilation and air exchanges throughout the hospice inpatient unit;
- (3.) emergency gas and water supply; and
- (4.) the scheduled and emergency maintenance and repair of all equipment.

(c.) Fire protection. Except as otherwise provided in this subsection:

- (1.) A hospice must meet the provisions applicable to the health care occupancy chapters of the 2000 edition of the LSC of the National Fire Protection Association (NFPA). Chapter 19.3.6.3.2, exception number 2 of the 2000 edition of the LSC does not apply to hospices.
- (2.) In consideration of a recommendation by HHSC, CMS may waive, for periods deemed appropriate, specific provisions of the LSC which if rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of clients.
- (3.) The provisions of the adopted edition of the LSC do not apply in the State of Texas if CMS finds that a fire and safety code imposed by State law adequately protects clients in hospices.
- (4.) Notwithstanding any provisions of the 2000 edition of the LSC to the contrary, a hospice inpatient unit may place alcohol-based hand rub dispensers in its facility if:
 - (A) use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;
 - (B) the dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;
 - (C) the dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(D) the dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the LSC, as amended by NFPA Temporary Interim Amendment 00-1(101), issued by the Standards Council of the NFPA on April 15, 2004.

- (d.) Client areas. A hospice inpatient unit must provide a home-like atmosphere and ensure that client areas are designed to preserve the dignity, comfort, and privacy of clients. A hospice inpatient unit must provide:
- (1.) physical space for private client and family visiting;
 - (2.) accommodations for family members to remain with the client throughout the night;
 - (3.) physical space for family privacy after a client's death; and
 - (4.) the opportunity for the client to receive visitors at any hour, including infants and small children.
- (e.) Client rooms. A hospice must ensure that client rooms are designed and equipped for nursing care, as well as the dignity, comfort, and privacy of clients. A hospice must accommodate a client and family request for a single room whenever possible. A client's room must:
- (1.) be at or above grade level;
 - (2.) contain a suitable bed and other appropriate furniture for the client;
 - (3.) have closet space that provides security and privacy for clothing and personal belongings;
 - (4.) accommodate no more than two clients and their family members; and
 - (5.) provide at least 80 square feet for a client residing in a double room and at least 100 square feet for a client residing in a single room.
- (f.) Toilet and bathing facilities. A client room in an inpatient unit must be equipped with, or conveniently located near, toilet and bathing facilities.
- (g.) Plumbing facilities. A hospice inpatient unit must:
- (1.) always have an adequate supply of hot water; and
 - (2.) have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by a client.
- (h.) Infection control. A hospice inpatient unit must maintain an infection control program that protects clients, staff, and others by preventing and controlling infections and communicable disease in accordance with §558.853 of this subchapter (relating to Hospice Infection Control Program).
- (i.) Sanitary environment. A hospice inpatient unit must provide a sanitary environment by following accepted standards of practice, including nationally recognized infection control precautions, and avoiding sources and transmission of infections and communicable diseases.

- (j.) Linen. A hospice inpatient unit must always have available a quantity of clean linen in sufficient amounts for a client's use. Linens must be handled, stored, processed, and transported in such a manner as to prevent the spread of contaminants.
- (k.) Meal service and menu planning. A hospice inpatient unit must furnish meals to a client that are:
 - (1.) consistent with the client's plan of care, nutritional needs, and therapeutic diet;
 - (2.) palatable, attractive, and served at the proper temperature; and
 - (3.) obtained, stored, prepared, distributed, and served under sanitary conditions.
- (l.) Use of restraint or seclusion. A client in a hospice inpatient unit has the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the client, a staff member, or others and must be discontinued at the earliest possible time.
 - (1.) Restraint or seclusion may only be used when less restrictive interventions are determined to be ineffective to protect the client, a staff member, or others from harm.
 - (2.) The type or technique of restraint or seclusion used must be the least restrictive intervention that is effective to protect the client, a staff member, or others from harm.
 - (3.) The use of restraint or seclusion must be:
 - (A) in accordance with a written modification to the client's plan of care; and
 - (B) implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospice policy.
 - (4.) The use of restraint or seclusion must be in accordance with the order of a physician authorized to order restraint or seclusion by hospice policy.
 - (5.) An order for the use of restraint or seclusion must never be written as a standing order or on an as needed basis.
 - (6.) The medical director or physician designee must be consulted as soon as possible if the attending practitioner did not order the restraint or seclusion.
 - (7.) An order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the client, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:
 - (A) four hours for adults 18 years of age or older;
 - (B) two hours for children and adolescents nine to 17 years of age; or
 - (C) one hour for children under nine years of age.

- (8.) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician authorized to order restraint or seclusion by hospice policy must see and assess the client.
- (9.) Each order for restraint used to ensure the physical safety of a non-violent or non-self-destructive client may be renewed as authorized by hospice policy.
- (10.) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.
- (11.) The condition of the client who is restrained or secluded must be monitored by a physician or trained staff who have completed the training criteria specified in subsection (o) of this section at an interval determined by hospice policy.
- (12.) Training requirements for a physician and for an attending practitioner must be specified in hospice policy. At a minimum, a physician and an attending practitioner authorized to order restraint or seclusion by hospice policy must have a working knowledge of hospice policy regarding the use of restraint or seclusion.
- (13.) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the client, a staff member, or others:
 - (A) the client must be seen face-to-face within one hour after the initiation of the intervention by a physician or RN who has been trained in accordance with the requirements specified in subsection (m) of this section; and
 - (B) the physician or RN must evaluate:
 - (i) the client's immediate situation;
 - (ii) the client's reaction to the intervention;
 - (iii) the client's medical and behavioral condition; and
 - (iv) the need to continue or terminate the restraint or seclusion.
- (14.) If the face-to-face evaluation specified in paragraph (13) of this subsection is conducted by a trained RN, the trained RN must consult the medical director or physician designee as soon as possible after the completion of the one-hour face-to-face evaluation.
- (15.) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion is only permitted if the client is continually monitored:
 - (A) face-to-face by an assigned, trained staff member; or
 - (B) by trained staff using both video and audio equipment. This monitoring must be close to the client.
- (16.) When restraint or seclusion is used, there must be documentation in the client's record of:

- (A) the one-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;
- (B) a description of the client's behavior and the intervention used;
- (C) alternatives or other less restrictive interventions attempted, if applicable;
- (D) the client's condition or symptoms that warranted the use of the restraint or seclusion; and
- (E) the client's response to the interventions used, including the rationale for continued use of the intervention.

(m.) Restraint or seclusion staff training requirements. A client has the right to safe implementation of restraint or seclusion by trained staff.

(1.) Client care staff working in the hospice inpatient unit must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a client in restraint or seclusion:

- (A) before performing any of the actions specified in paragraph (1) of this subsection;
- (B) as part of orientation; and
- (C) subsequently on a periodic basis consistent with hospice policy.

(2.) A hospice must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the client population in:

- (A) techniques to identify staff and client behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion;
- (B) the use of nonphysical intervention skills;
- (C) choosing the least restrictive intervention based on an individualized assessment of the client's medical or behavioral status or condition;
- (D) the safe application and use of all types of restraint or seclusion used in the hospice, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
- (E) clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary;
- (F) monitoring the physical and psychological well-being of a client who is restrained or secluded, including but not limited to respiratory and circulatory status, skin integrity, vital signs, and any special requirements

specified by hospice policy associated with the one-hour face-to-face evaluation; and

(G) the use of first-aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3.) Persons providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address a client's behaviors.

(4.) A hospice must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(n.) Death reporting requirements. A hospice must report deaths associated with the use of seclusion or restraint in its inpatient unit.

(1.) The hospice must report:

(A) an unexpected death that occurs while a client is in restraint or seclusion;

(B) an unexpected death that occurs within 24 hours after the client has been removed from restraint or seclusion; and

(C) a death known to the hospice that occurs within one week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to the client's death. The term "reasonable to assume" in this context includes but is not limited to death related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2.) The hospice must report a death described in paragraph (1) of this subsection to HHSC by telephone at 1-800-458-9858 within 24 hours after knowledge of a client's death.

(3.) The hospice must complete Provider Investigation Report For Home and Community Support Services Agency (HHSC Form 3613) and send it to HHSC Complaint Intake Unit within 10 days after reporting the death to HHSC by telephone.

(4.) Hospice personnel must document in the client's record the date and time the death was reported to HHSC.

Division 8 Hospices that Provide Hospice Care to Residents of a Skilled Nursing Facility, Nursing Facility, or Intermediate Care Facility for Individuals with an Intellectual Disability or Related Conditions

§558.880 Providing Hospice Care to a Resident of a Skilled Nursing Facility, Nursing Facility, or Intermediate Care Facility for Individuals with an Intellectual Disability or Related Conditions

- (a.) Professional management. A hospice must assume responsibility for professional management of the hospice services it provides to a resident of a skilled nursing facility (SNF), nursing facility (NF), or an intermediate care facility for individuals with an intellectual disability or related conditions (ICF/IID), in accordance with the hospice plan of care. The hospice must make arrangements, as necessary for hospice-related inpatient care in a participating Medicare or Medicaid facility, in accordance with §558.850 of this subchapter (relating to Organization and Administration of Hospice Services) and §558.863 of this subchapter (relating to Hospice Short-term Inpatient Care).
- (b.) Written contract. A hospice and SNF, NF, or ICF/IID must have a written contract that allows the hospice to provide services in the facility. The contract must be signed by an authorized representative of the hospice and the SNF, NF, or ICF/IID before hospice services are provided. In addition to the requirements in §558.289 of this chapter (relating to Independent Contractors and Arranged Services), the written contract must include:
 - (1.) the way the SNF, NF, or ICF/IID and the hospice are to communicate with each other and document such communications to ensure that the needs of a client are addressed and met 24 hours a day;
 - (2.) a provision that the SNF, NF, or ICF/IID immediately notifies the hospice of:
 - (A) a significant change in the client's physical, mental, social, or emotional status;
 - (B) clinical complications that suggest a need to alter the plan of care;
 - (C) the need to transfer the client from the SNF, NF, or ICF/IID; or
 - (D) the death of a client;
 - (3.) a provision stating that if the SNF, NF, or ICF/IID transfers the client from the facility that the hospice arranges for, and remains responsible for, any necessary continuous care or inpatient care related to the terminal illness and related conditions;
 - (4.) a provision stating that the hospice assumes responsibility for determining the appropriate course of hospice care, including the determination to change the level of services provided;
 - (5.) an agreement that the SNF, NF, or ICF/IID is responsible for furnishing 24-hour room and board care, meeting the personal care and nursing needs that would have been provided by the primary caregiver at home at the same level of care provided before the client elected hospice care;

- (6.)an agreement that the hospice is responsible for providing services at the same level and to the same extent as those services would be provided if the SNF, NF, or ICF/IID resident were in his or her own home;
 - (7.)a delineation of the hospice's responsibilities, which include providing medical direction and management of the client; nursing; counseling, including spiritual, dietary and bereavement counseling; social work; medical supplies, durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions;
 - (8.)a provision that the hospice may use the SNF, NF, or ICF/IID nursing personnel where permitted by State law and as specified by the SNF, NF, or ICF/IID to assist in the administration of prescribed therapies included in the plan of care, only to the extent that the hospice would routinely use the services of a hospice client's family in implementing the plan of care;
 - (9.)a provision stating that the hospice must report an alleged violation involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client property by non-hospice personnel to the SNF, NF, or ICF/IID administrator within 24 hours after the hospice becomes aware of the alleged violation;
 - (10.) a delineation of the responsibilities of the hospice and the SNF, NF, or ICF/IID to provide bereavement services to SNF, NF, or ICF/IID staff; and
 - (11.) a provision regarding management and disposal, in compliance with applicable law, of drugs, including controlled substance prescription drugs and biologicals.
- (c.) Hospice plan of care. In accordance with §558.821 of this subchapter (relating to Hospice Plan of Care), a written hospice plan of care must be established and maintained in consultation with SNF, NF, or ICF/IID representatives. Hospice care must be provided in accordance with the hospice plan of care.
- (1.)A hospice plan of care must identify the care and services needed to care for the client and specifically identify which provider is responsible for performing the respective functions that have been agreed upon and included in the hospice plan of care.
 - (2.)A hospice plan of care must reflect the participation of the hospice, representatives of the SNF, NF, or ICF/IID, and the client and family to the extent possible.
 - (3.)Any changes in the hospice plan of care must be discussed with the client or the client's LAR, and SNF, NF, or ICF/IID representatives, and must be approved by the hospice before implementation.
- (d.)Coordination of services. In addition to the requirements in §558.288 of this chapter (relating to Coordination of Services) and §558.823 of this subchapter (relating to Coordination of Services by the Hospice), a hospice must:

- (1.) designate a member of each interdisciplinary team (IDT) that is responsible for a client who is a resident of a SNF, NF, or ICF/IID who is responsible for:
 - (A) providing overall coordination of the hospice care of the SNF, NF, or ICF/IID resident with SNF, NF, or ICF/IID representatives; and
 - (B) communicating with SNF, NF, or ICF/IID representatives and other health care providers participating in the provision of care for the terminal illness and related conditions and other conditions to ensure quality of care for the client and family; and
- (2.) ensure that the hospice IDT communicates with the SNF, NF, or ICF/IID medical director, the client's attending practitioner, and other physicians participating in the provision of care to the client as needed to coordinate hospice care with medical care provided by other physicians; and
- (3.) provide the SNF, NF, or ICF/IID with:
 - (A) the most recent hospice plan of care specific to the client;
 - (B) the hospice election form and any advance directives specific to the client;
 - (C) physician certification and recertification of the terminal illness specific to the client;
 - (D) names and contact information for hospice personnel involved in hospice care of the client;
 - (E) instructions on how to access the hospice's 24-hour on-call system;
 - (F) hospice medication information specific to the client; and
 - (G) hospice physician and, if any, attending practitioner orders specific to the client.
- (e.) Orientation and training of staff. Hospice personnel must ensure that SNF, NF or ICF/IID staff who provide care to the hospice's clients have been oriented and trained in the hospice philosophy, including the hospice's policies and procedures regarding methods of comfort, pain control, and symptom management, as well as principles about death and dying, how a person may respond to death, the hospice's client rights, the hospice's forms, and the hospice's record keeping requirements.
- (f.) Management and disposal of drugs and biologicals. The policies and procedures of the hospice may not impede the SNF, NF, or ICF/IID from adhering to state, federal, and local law applicable to the disposal of drugs and biologicals in a facility.